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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1967

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DR. F. ALLEN RUTHERFORD, Louise Walther, Sally Ranich, Vera Mae Jeffries, C. R. Easter, Dorothy Williams, each in behalf of their own person, and in behalf of all persons afflicted with cancer, and approximately thirty-two million Americans now living who will die with cancer,

*Petitioners,*

vs.

THE AMERICAN MEDICAL ASSOCIATION, INC., an Illinois Corporation, The American Cancer Society, Inc., a New York Corporation, The American Cancer Society, San Francisco Division, California, and Dr. ———— Batchelder (first name unknown) and

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, Dr. Warren G. Cole, Dr. Danley Slaughter, Dr. Virginia Pierce, Dr. George D. Stoddard, and

DR. KENNETH M. ENDICOTT, Arthur Furst, Paul Kirk, Gene R. Hay, Michael Deddish, Joseph M. Regan, Guy F. Robbins, Albert Segaloff, Austin Smith, Henry A. Szujewski, Paul Wermer, Oliver Field, R. Edwin Moore, Daniel Abrahamson, John William Blue, Mrs. John W. Blue, Carl R. Baurlen, William E. Braunig, R. W. Case, Joseph Cox, Gilbert Goldhammer, John R. Heller, William Kupp, Boisfeullet Jones, George P. Larrick, T. C. Maariveglia, Howard Mayfield, Willard G. Orr, Robert Palmer, Thomas Rice, George Schwartzman, Clifford Shane, R. D. Sherman, Ted J. Smolenski, Norman P. Booker, and other persons unknown,

*Respondents.*

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## PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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**PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT**

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Petitioners pray that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Seventh Circuit entered in the above case on June 23, 1967.

## OPINION BELOW

The opinion of the Court of Appeals for the Seventh Circuit is reported at 379 F. 2d 641; and is printed in the Appendix hereto, *infra*, App. 1-7; and the unreported opinion of the District Court in Appendix at *infra*, pp. App. 8-16.

## JURISDICTION

The jurisdiction of this Court is invoked under 28 U.S.C. Section 1254(1).

## QUESTIONS INVOLVED

1. Where the proximate consequences of the criminal conspiracy allegedly conducted by the respondents in violation of the antitrust laws, is actual and threatened loss and damage to the lives and rights of the petitioners, are the petitioners entitled to sue for and have injunctive relief against such threatened loss and damage under section 26, Title 15, U.S.C.?

2. Whether private corporations and private individuals, acting in association with public officials under color of law from the University of Illinois, in a criminal conspiracy in violation of the antitrust laws, come within the scope of sections 1983-1985, Title 42, U.S.C.

3. Where a corporation, such as the American Medical Association, vested with sufficient economic power and influence concentrated in this State-created vehicle to invade the rights secured by the Constitution and laws of the United States of 200,000 Americans to a material degree,

conducts a criminal conspiracy in violation of the antitrust laws, does such wrongful conduct come within the prohibitions contained in the Fourteenth Amendment?

4. Whether a corporation, such as the American Cancer Society which, to a material degree, has substantial control of research on cancer in the United States, and exclusively exists on grants-in-aid funds from Federal and State Governments, and tax exempt and tax deductible contributions from the public, when it is associated with another corporation, four State University Officials, and a series of individuals in a criminal conspiracy which violates the antitrust laws, comes within the scope of the prohibitions of the Fourteenth Amendment.

5. Whether the toleration of a "monopoly in the trade of medicine" by the American Medical Association is legally and socially defensible and justified when perverted so as to conduct, with others in this case, a criminal conspiracy in violation of the antitrust laws "of vigilante-like activities", restraining doctors in pursuit of their calling, depriving them of hospital facilities for their patients, threatening them with disciplinary action, excluding them from hospital staffs, both in private and State hospitals, depriving them of consultation with other members of the profession on pain of expulsion, because of administering or seeking to administer to their patients in scientific and experimental research, a therapy legally in interstate distribution for such purpose, which they believed and still believe showed and shows promise of making valuable contributions to human knowledge in the cause and treatment of cancer; and further, is the toleration of such monopoly when so exercised in such a conspiracy, hus defensible and justified even if such interstate distribution is forbidden by law.

6. Whether such a conspiracy is defensible because the therapy has not been approved under the Federal Food, Drug, and Cosmetic Act, and because the respondents disagree with the scientific expertise of the Department of Health, Education, and Welfare and its determinations twice in 1954, and once in 1961, that the therapy, because of its components, does not come within the provisions of that Act but under the Public Health Service Act of 1944, and that nothing could be gained by any application to the provisions of the former.

7. Whether, in amending section 355 (i), Title 21, U.S.C., in October 1962, effective in June 1963, Congress set up such a right, which respondents claim as their sole defense, as to justify such a criminal conspiracy, both retroactively from its conception in 1950, and in the present.

8. Whether, the determinations of the Department of Health, Education, and Welfare, based on the conclusions of its scientific expertise made on May 25, 1954, August 12, 1954, and on June 9, 1961, that Krebiozen, because of its components, "is subject to the Virus, Serum, and Toxin provisions of the Public Health Service Act of July 1944," and that "Nothing is to be gained by considering the product as a new drug under the Food, Drug, and Cosmetic Act," and that "Our scientists, on the information submitted, classify this drug as an 'analogous product' within the meaning of the Public Health Service Act," and that "We recommend that you abandon the idea of pursuing an effective new drug application and submit an appropriate application for licensing of Krebiozen by the Division of Biologic Standards," may be completely ignored or overruled by the respondents and the courts below as a refutation of their defense to the allegations of such a criminal conspiracy.

9. Whether section 262, Title 42, U.S.C., the Public Health Service Act, a highly penal statute, directed against persons who "sell, barter, or exchange, or offer for sale, barter, or exchange," in interstate commerce, is applicable to articles which come within the provisions of the Act, but are distributed interstate, not for "sale, barter, or exchange," but for use in scientific and experimental research, with the elements of "sale, barter, or exchange," precedent to a conviction under the statute, totally absent.

10. Whether the amendment of section 355 (i), Title 21, U.S.C., effective June 1963, expressly limited to drugs where there can be a valid "event of the filing of an application pursuant to subsection (b) of this section," to put the article in interstate commerce, can be extended by regulation, unauthorized by legislation, to articles like Krebiozen, where the only valid "event" for introducing the article in interstate commerce is an application pursuant to section 262, Title 42, U.S.C., as has been thrice determined by the Department of Health, Education, and Welfare.

11. Whether Congress has, in such amendment enacted a law not naturally or reasonably adapted to the power conferred by the Commerce Clause, but solely adapted to the achievement of the regulation of the practice of medicine which is reserved solely to the States and the People, by the Ninth and Tenth Amendments, and which practice involves no elements of commerce.

12. Whether such a criminal conspiracy of official lawlessness as the record here reveals, dedicated and calculated to effectively stifle independent initiative and originality in the "Progress of Science and the useful Arts," and designed to impede and hinder those already skilled in the profession of medicine, to attempt new

methods of treatment for cancer, when all other known methods have proved futile, and particularly when the patient's life has been despaired of, especially when undertaken with the patient's full knowledge and consent, and as a last resort, violates Article 1, section 8, the Fifth, Ninth, Tenth, and Fourteenth Amendments of the Constitution, and is of such immense social significance as to warrant review by this Court on certiorari.

13. Whether *Turkel* v. *Food and Drug Administration,* 334 F. 2d 844, where the subject matter comes under a different law because it deals with an essentially different product, subject to different regulations, have any application here.

14. Whether the District Court did not commit a fatal error on May 13, 1966, when it denied to the petitioners the right to file a verified petition for a mandatory temporary injunction under Rule 65, Federal Rules of Civil Procedure, and a finding of facts and conclusions of law as mandatorily provided by Rule 52, despite the fact that the petition supported by affidavits and exhibits made a strong showing that irreparable damage to the health and lives of the petitioners was imminent, and which denial has directly contributed to the death of three of the petitioners since that time.

15. When it was brought to the notice of the District Court on February 4, 1966 by counsel for the petitioners that if a temporary restraining order or temporary injunction was not issued the lives of the petitioners would be in peril because of the criminal conspiracy, and the motion was denied on the grounds "This matter has been going on for a number of years, so there cannot be that kind of an emergency here today," not a fatal error.

16. Whether a citizen afflicted by disease, and especially when declared terminal, has a constitutional right under the Fifth, Ninth and Fourteenth Amendments to freedom of access of a non-toxic medical remedy of his own choice regardless of sanction thereto by the American Medical Association or Governmental Agencies or bureaucrats.

17. Whether the Federal Food Drug and Cosmetic Act, as amended in 1961, is unconstitutional because violating the rights of individuals, under the Fifth, Ninth and Fourteenth Amendments to the United States Constitution, whose survival depends upon unfettered access to a new drug, because such Act permits an arbitrary and judicially non-appealable denial of an application for investigational exemption therefrom and permits half a year's delay by the Secretary of Health, Education and Welfare in consideration of an application for approval of interstate distribution and further fatal delay in administrative and judicial appeals to an arbitrary refusal of such application.

## CONSTITUTION, STATUTES, FEDERAL RULES OF CIVIL PROCEDURE, AND DRUG REGULATIONS INVOLVED.

Involved herein are the following: Amendments Five, Nine, Ten, and Fourteen of the Constitution of the United States App. F., App. 29 in Appendix; Section 26, Title 15, U.S.C.; Section 355, Title 21, U.S.C., Section 1331, 1343, Title 28, U.S.C., Sections 262, 284, 1983, 1984, 1985, Title 42, U.S.C.; Federal Rules of Civil Procedure 52 and 65; Food and Drug Regulations 130.3, all in appendix pp. App. 22-39.

## STATEMENT

This suit was commenced on January 3, 1966 in the United States District Court in Chicago by the filing of a Complaint praying for a Mandatory Injunction against the Respondents.

On January 10th and 13th, 1966, the petitioners filed with the District Court two petitions for temporary restraining orders returnable on Jannay 19, 1966 (Vol. II, pp. 326-334, R.)

On January 19, 1966 the case was continued until February 4, 1966.

On February 4, 1966, the petitions for the restraining orders were denied (Vol. II, 326-385, R).

On May 6, 1966, the petitioners filed with the District Court a Verified Petition For A Mandatory Temporary Injunction. On May 13, 1966, the District Court ordered the Clerk to delete the filing numbers from the petition and denied the petitioners the right to file the Petition (Vol. II, 501-512, R).

On July 18, 1966, the Complaint was dismissed with an opinion (Copy annexed at pp. App. 8-16).

On July 26, 1966, the petitioners filed notice of appeal to the Court of Appeals (Vol. II, 540-543, R).

On November 2, 1966 the Court of Appeals denied a petition for a temporary injunction pending appeal (Vol. III, p. 221).

On June 23, 1967, the Court of Appeal affirmed the decision of the District Court with opinion reported at 379 F. 2d 641, (copy in appendix, pp. App. 1-7).

On September 13th, 1967, Mr. Justice Fortas granted the petitioners an extension of time up to and including November 19, 1967 in which to file petition for certiorari in this Court (copy of order in appendix at p. App. 40).

## SUMMARY OF ALLEGATIONS

1. Krebiozen upon its original introduction in this country by Dr. Stevan Durovic in 1949 having already shown promise in extensive animal research, showed promise in the control of cancer in man. It was used experimentally on terminal patients by a number of doctors and institutions such as Lankenau Hospital Research Institute of Philadelphia (See Exhibit 3 of Amended Complaint for their favorable report; Amended Complaint Vol. 1) the Marquette Tumor Clinic, the Walter Reed Hospital and Johns Hopkins Hospital.

Dr. Andrew C. Ivy, who had for a long time been interested in cancer research, and had postulated that cancer, although manifesting itself in differing symptoms was possibly caused by a single fundamental body deficiency, investigated Krebiozen with, to him, remarkable results and recoveries in apparently hopeless cancer patients. (This is outlined in pp. 42, 46, paragraphs 154 and 176, Amended Complaint Vol. I).

2. The initial phase in the criminal conspiracy alleged in the Amended Complaint commenced when several of the perennial officers of the American Association, learning of the promise of Krebiozen endeavored to obtain its commercial control for them and their business associates. They were rebuffed by Dr. Durovic and his brother who was financing him. (This phase of the conspiracy it outlined in pages 39 through 46 paragraphs 143-146 and 153-176, Amended Complaint, Vol. 1). From then on these men commenced a systematic campaign to destroy Krebiozen.

During this time Dr. Ivy and his associates endeavored to have a committee of scientists sponsored by the American Medical Association, review his experience with Krebiozen and that of the above mentioned institutions and hospitals. On the request of the American Medical Association he submitted 140 representative clinical records of patients he had treated with Krebiozen (See pages 50 and 51, paragraphs 197-203, Amended Complaint, Vol. 1).

3. The initial phase in the alleged criminal conspiracy culminated in what was classified as the Status Report on Krebiozen by the American Medical Association and was published in the Journal of the American Medical Association on September 27, 1951. As was subsequently revealed under oath at Hearings held before an Illinois Legislative Committee this Report was a deliberate fraud, and was designed and calculated to suppress the anticancer nontoxic therapy named Krebiozen. This therapy showed promise of making valuable contributions to human knowledge in the cause and treatment of cancer, but if it should prove effective and be introduced into medicine it would be in economic conflict with such alleged therapies as surgery, radiation, cobalt, and highly toxic therapies, all of which are applied to the effects of the disease, and not the cause, and all in complete control of the Respondent, the American Medical Association. This phase of the conspiracy consumed about a year and was conducted by the conspirator Dr. J. J. Moore, the Respondents Dr. Austin Smith, Dr. Paul Wermer, and Oliver Field, and others unknown, acting as officers of the American Medical Association, and in concerted action with the Respondent R. Edwin Moore, a private individual, Dr. Albert Segaloff, representing the Oschner Cancer Clinic of New Orleans, the Respondent Dr. Henry A. Szujewski all in behalf of the American Medical Association, and the Respondents Dr.

Warren G. Cole, Dr. Virginia Pierce, and Dr. Danley Slaughter, acting "under color" of law from the University of Illinois, and in concerted action with the Respondent, the American Medical Association. This phase represented the suppression completely of the 140 clinical case records which, had been by agreement between Dr. Andrew C. Ivy and the American Medical Association, would be used as the base on which to determine the effectiveness of Krebiozen in the control of cancer. These clinical records of patients who had been treated with Krebiozen came from some of the most reputable hospitals in the United States, and all of them, without exception, indicated that the therapy did show promise of making valuable contributions to human knowledge in the treatment of the disease. Twenty four additional clinical records of patients treated with Krebiozen were submitted by Dr. Andrew C. Ivy. These records came from a private physician from Chicago named Dr. William F. Phillips. Like the 140 clinical records from the hospitals, these records from Dr. Phillips also indicated that this therapy showed promise in controlling cancer. The Respondent Dr. Henry A. Szujewski forged and uttered 23 out of the 24 clinical records to make it appear otherwise. The conspirator Dr. J. J. Moore, and the Respondents Dr. Austin Smith, Dr. Paul Wermer from the American Medical Association, Dr. Albert Segaloff from the Oschener Cancer Clinic of New Orleans, and Dr. Warren G. Cole, Dr. Virginia Pierce, acting "under color" of law from the University of Illinois through the Illinois Tumor Clinic, then implemented a common scheme and plan systematically to select from these clinics and others, the clinical records of cancer patients who were on the edge of the grave and could not, and did not, live long enough to receive in some instances more than one, and in no instance more than four, injec-

tions of Krebiozen. All those patients who had received more injections of the therapy and where it did show promise of making valuable contributions to human knowledge in the treatment of cancer were systematically disregarded. 100 clinical records of the former were used for the investigation. On these systematically selected clinical records the determination was based. They numbered 76 and with the 24 clinical records, 23 of which Dr. Henry A. Szujewski had uttered the Status Report of Krebiozen was grounded. All this was subsequently also revealed under oath at the Hearings held before the Illinois Legislative Committee. As a follow-up of this fraudulent and partly uttered Status Report, on the instructions from the conspirator Dr. J. J. Moore and Dr. Paul Wermer, Dr. Henry A. Szujewski wrote another article in the Journal of the American Medical Association which was published on March 27 1952. This article was also false. (The acts of each and every one of these Respondents in this phase of the conspiracy and fraud are outlined with particularity in pp. 33-66, paragraphs 143-269, Amended Complaint, Vol. 1).

4. The next phase in the criminal conspiracy and directly linked with phase one, culminated in the publication of the "Conclusions" and "Recommendations" purportedly drawn from the Report of the Krebiozen Validating Committee by the University of Illinois and released to the world by the Respondents Dr. George D. Stoddard and Dr. Warren G. Cole on September 20, 1952. Both the "Conclusions" and the "Recommendations" were a fraud because they were not those of the Committee, were not based on the facts of the "Main Report" of the Committee, were not authorized by the Committee, were not signed by any of the other five members of the Committee, and no

member of the Committee knew of the release until it was a *fait accompli.* The Respondent Dr. George D. Stoddard, because the Main Report of the Committee indicated from the physical examination of a series of cancer patients by members of the Committee and a great many clinical records which were presented to the Committee that Krebiozen did show promise of making valuable contributions to human knowledge in the cause and treatment of cancer, suppressed and hid the Main Report, and even refused Dr. Andrew C. Ivy to examine the Main Report. Over one month after the release of the "Conclusions" and "Recommendations" by Dr. George D. Stoddard and the Respondent Dr. Warren G. Cole, on the instructions of the conspirator Dr. J. J. Moore, and the Respondent Dr. Paul Wermer, the five other members of the Committee, Dr. N. C. Gilbert, Dr. Fred Hodges, Dr. Robert W. Keeton, Dr. Paul Steiner, and Dr. Owen H. Wangensteen, were compelled to sign a blank signature sheet, without having been permitted to even read a copy of the "Recommendations." The single sheet was sent out by the Respondent Dr. George D. Stoddard in a chain form letter to these members of the Committee (The facts which constitute this phase of the fraud and conspiracy are outlined with particularity in pp. 66-97, paragraphs 270-407, in the Amended Complaint, Vol. 1, Record. The facts are borne out by sworn testimony in the subsequent Hearings of the Committee of the Illinois General Assembly).

5. In March, 1954, the sponsors of Krebiozen filed an application under subsection 355 (b) of Title 21, U.S.C.A. (The Federal Food, Drug, and Cosmetic Act) in order to place Krebiozen in interstate commerce. On May 25th, 1954, the application was rejected on the grounds that " . . . it is the considered view of the Department of Health,

Education, and Welfare that Krebiozen is subject to the Virus, Serum, Toxin provisions of visions of the Public Health Service Act of July 1944, and that the article may not be legally marketed in interstate commerce until licensed under the provisions of that Act. #. . . When a license is issued by that unit of the Department, an effective new drug application is not required. #Even if a new drug application became effective for the article, it would still be necessary that it be licensed under the provisions of the Public Health Service Act in order that it be distributed in interestate commerce. #Nothing is to be gained by considering the product (Krebiozen) as a new drug under the Food, Drug, and Cosmetic Act."

6. Shortly after the scientific determination was made by the Department of Health, Education, and Welfare that Krebiozen was not a "new drug" within the provisions of the Federal Food, Drug, and Cosmetic Act, but came exclusively within the provisions of the Public Health Service Act which is Section 262, Title 42, U.S.C.A., the sponsors of Krebiozen offered more data to show that Krebiozen did come within the provisions of the Federal Food, Drug and Cosmetic Act. The Department of Health, Education, and Welfare, on August 12, 1954, reiterated its former scientific determination of May 25, 1954 that: "Our scientists, on the information submitted, classify this drug (Krebiozen) as an 'analogous product' within the meaning of the Public Health Service Act. #Since the drug, in the Department's view, may not be distributed for barter or sale unless produced in a licensed establishment, we recommended to you in our letter of May 25, that you take the problem up with the Laboratory of Biologics Control rather than pressing for an effective new drug application . . . #We do not insist on the needless dublication of satisfying the requirements of both laws. We do insist,

however, that products subject to license control meet the requirements of the Public Health Service Act. . . . #We renew our recommendation that you take steps to obtain a license rather than making further efforts to complete the new drug application." After this second determination of the scientific expertise of the Department of Health, Education, and Welfare, the sponsors of Krebiozen limited interstate distribution of Krebiozen to doctors throughout the United States who were fully qualified by scientfic training and experience to investigate the safety and effectiveness of drugs, but not for "sale, barter, or exchange" exclusively for "use in scientific and experimental research." This was in strict conformity with section 262, Title 42, U.S.C.A. (The Public Health Service Act) and with the ruling by the Attorney General in 29 Opinion of Attorney General 340.

7. Shortly thereafter the determination of the scientific expertise of the Department of Health, Education, and Welfare, Dr. Andrew C. Ivy, the scientific sponsor of Krebiozen received a grant-in-aid from the Lakeland Foundation of Chicago for the purpose of producing Krebiozen to carry out this program of "scientific and experimental research". The American Medical Association then launched another phase of the continuing conspiracy, to prevent this program from being implemented, through its chief security officer, the Respondent, Oliver Field. The facts which constitute this phase are stated with particularity at pp. 97-106, paragraphs 408-466, Amended Complaint, Vol. 1, Record). Simultaneously in this phase, the American Medical Association launched a campaign of harassment against doctors using the therapy and patients receiving it. The harassment tactics employed against these doctors and their cancer patients had a striking similarity to the tactics used by the Respondent,

the American Medical Association and its affiliated medical societies in the criminal conspiracy against Group Insurance outlined in the indictment of *American Medical Association* v. *United States*, 317 U.S. 519, at pages 7-19, Volume 1, Record on Certiorari, on file in this Court.

8. As the result of the Hearings by the Illinois General Assembly the first report of that Assembly was handed down on June 30, 1955 and the following public policy was adopted by the Legislative Body for the State of Illinois to further investigate Krebiozen because "It is evident there are citizens in Illinois and other states and countries who are or have been afflicted with the dread disease, cancer, and who received treatment by medical practitioners by the use of the drug Krebiozen and are today alive and well; and after a period of ten years, Krebiozen continues to hold out very substantial promise and assurance that there must exist merit and truth within the drug Krebiozen to manage and control cancer in the patient;" (pp. 96-97, paragraphs 403-407, Amended Complaint, Vol. 1, Record).

9. Subsequent to the first report of the Illinois Legislative Assembly and the harassment by the American Medical Association through its chief security officer, the Respondent, Oliver Field, the conspiracy changed venue to New York and California and involved the Respondent, the American Cancer Society, the Respondents, Dr. Batchelder, the Chairman of its San Francisco branch, Arthur Furst, Paul Kirk, and Dr. John R. Heller, the latter of whom held positions involving a conflict of interest. He was both director of the American Cancer Society and at the same time was the director of the Government Health Institution, the National Cancer Institute, and was being paid for both. For all practical purposes Dr. John R.

Heller is the first connecting link with private individuals and private corporations on one hand, and individuals employed by the United States Government on the other hand. After negotiations between Dr. Andrew C. Ivy the scientific sponsor of Krebiozen and representatives of the American Cancer Society, the latter undertook to formulate a paper on "The Background of Krebiozen," despite the fact that any favorable Report on the non-toxic therapy Krebiozen if favorable would be in economic conflict with the vested interests of the American Cancer Society. At the time, this Society owned about 50% of the highly toxic anticancer substance known as 5-FU and if it was determined that Krebiozen did show great promise of making valuable contributions to human knowledge in the cause and treatment of cancer this would render the highly economic vested interest in 5-FU by the American Cancer Society at naught. For this reason the American Cancer Society proceeded to condemn Krebiozen in a studied campaign to falsify and a premeditated determination to so condemn. The facts which constitute the fraud and conspiracy are outlined with particularity as to each Respondent involved in this phase in pp. 107-138, paragraphs 447-595, Amended Complaint, Vol. 1, Record). In pursuance of this plan the "Paper on the Background of Krebiozen" was issued on March 9, 1959 condemning Krebiozen.* While the so-called

* As later determined this paper was in fact based upon the perjured statements of two "researchers" to the effect that with no more than six unregistered ampules they had conducted very many and radically differing exhaustive tests, which however, scientifically, would have required at least several hundred valid ampules and had "found" that Krebiozen is no more than "mineral oil".

investigation was pending the Respondent, Dr. John R. Heller had been conducting negotiations with Dr. Andrew C. Ivy with the objective of a "double blind" test for Krebiozen by the National Cancer Institute. But as Dr. Heller had voted as a paid director of the Respondent, the American Cancer Society, and in full awareness of how that determination was brought about by fraud and misrepresentation, he was in no position to overrule it as the director of the National Cancer Institute. Prior to the voting for the condemnation of Krebiozen he had agreed with the sponsors of the substance that the double-blind test was "the standard of evaluation at the National Cancer Institute." He had now voted with the American Cancer Society as its director that the double-blind test was "unscientific." Further negotiations for a test as provided by section 284, Title 42, U.S.C.A. (The Public Health Service Act) where the scientific expertise of the Department of Health, Education, and Welfare determined that Krebiozen had belonged were futile. In 1960 Dr. Heller ceased his role of conflicting interests and retired as director of the National Cancer Institute to take an executive position with Sloan-Kettering Memorial Institute in New York. He was replaced as director of the National Cancer Institute by the Respondent, Dr. Kenneth M. Endicott on July 1, 1960.

10. The sponsors of Krebiozen immediately commenced negotiations with the Respondent, Dr. Endicott for a test of the therapy under section 284, Title 42, U.S.C.A. Dr. Endicott agreed to have the National Cancer Institute test the drug, Krebiozen, as provided by that statute. See pages 138-148, paragraph 596-647, Amended Complaint, Vol. 1, Record. Adequate data to be used as a guide to the test was submitted to Dr. Endicott on or about October 20, 1960, at a meeting with all the parties in the Lord

Baltimore Hotel, Baltimore, Maryland (p. 146, par. 637, Amended Complaint) and it was further clearly understood between Dr. Endicott and the sponsors that the material and data submitted to Dr. Endicott by the sponsors was to be used as a guide to the test agreed upon, and would not be submitted to any committee to decide whether or not a test would be made. Instead of honoring the agreement, Dr. Endicott gave the data, which contained the names of over 3,000 physicians over the United States who had successfully treated their patients with Krebiozen, over to the Respondent, George Larrick, who immediately launched a wide-spread harassment campaign against these doctors and their patients never before heard of in the entire history of the suppression of innovation in the medical world. Simultaneously with this campaign of harassment was also launched a widespread campaign of entrapment practices against the sponsors of Krebiozen and many of the doctors. The phase culminated in a secret committee of systematically selected scientists, half of whom depended on Dr. Endicott for their income from Government grants approved by Dr. Endicott, in a predetermined scheme and plan to condemn Krebiozen without a hearing. This phase of the conspiracy and fraud is outlined with particularity as to each and every respondent involved in its execution in pp. 148-225, paragraphs 648-1014, Amended Complaint, Vol. 1, Record.

11. Early in 1961 the sponsors of Krebiozen again filed an application under the Federal Food, Drug, and Cosmetic Act, section 355 (b), Title 21, U.S.C.A. to place the substance in interstate commerce. This was again rejected in June, 1961 by the Department of Health, Education and Welfare on the grounds that the substance did not come within the provisions of this Act, and the Department stated that : "We recommend that you abandon the

idea of pursuing an effective new drug application and submit an appropriate application for licensing by the Division of Biological Standards, National Institutes of Health, U. S. Public Service." However, were it not for the determination of the Department of Health, Education and Welfare that Krebiozen is not a new drug and does not come under the Federal Food, Drug and Cosmetic Act, that application under that Act would be effective today because the Secretary failed to comply with the provisions of Section 355 (c) of that Act and as a result, by reasons of the terms of the Act the application became automatically effective upon the expiration of the prescribed statutory time.

12. Thereafter on September 7, 1963, the Food and Drug Administration publicly released a report that it had determined that Krebiozen was (not mineral oil but) only Creatine, a harmless but ineffective body substance. This report used infra-red spectograph overlays patently juggled by seven and one-half percent to force coincidence of graph lines and disregarded gross chemical differences in acids, sugars, molecular weight and carbon content between Krebiozen and Creatine which were already known to that administration and the National Cancer Institute. (This phase of the conspiracy and fraud is outlined in pages 171 through 182, paragraphs 777 through 818 and page 189, paragraphs 856 through 858, Amended Complaint Vol. I).

13. Thereafter on October 16, 1963, the National Cancer Institute published a report of a Secret Committee of 24 doctors (of whom it was later determined 8 were on the United States Government payroll and the other 16 were recipients of large Government research grants). This report, which was expressly based on the Food and Drug Administration that Krebiozen is only ineffective creatine,

denied that any weight should be given to its value as a pain reliever (because pain, being subjective, is not susceptible of objective proof) and, after scrambling the identification numbers of the cases, disregarding 216 cases without disclosed justification (of which 15 were later determined to be very favorable breast cancer cases), of the remainder all where 50% or less reduction of tumor (even though still continuing) were involved and of 15 cases nevertheless meeting these uniquely restrictive standards disregarded all but two by increasing the unique and irrational severity of the standards applied and concluded that the remaining two were due to spontaneous regression (notwithstanding that hitherto the classic Cole-Everson study of four and one-half million cancer cases indicated that spontaneous regression occurs in only one out of 80,000 to 100,000 cases). (This phase of the conspiracy and fraud is outlined in pages 153 through 171, paragraphs 699 through 776 and pages 184 through 222, paragraphs 829 through 1007, Amended Complaint, Vol. I).

14. Dr. Ivy and his associates were refused publication in any medical journals controlled by the American Medical Association of numerous, voluminous, scientifically exhaustive articles on clinical and experimental experience with Krebiozen and finally had to resort to private publication. Having denied him and his associates such publication, the American Medical Association then criticized Krebiozen, on the grounds that no papers on it had been published in their authoritative Medical Journals (See pages 135 through 137, paragraphs 584 through 593, Amended Complaint, Vol. I).

## REASONS FOR GRANTING THE WRIT

The subjects in the numbered paragraphs here correspond with the subjects in the same numbered paragraphs in the "QUESTIONS INVOLVED."

1. The petitioners are entitled to sue for and have injunctive relief under section 26, Title 15, U.S.C.A.

It has been well settled in this Court that the Sherman-Clayton Act gives to private persons he right to sue for and have injunctive relief against threatened loss or damage by violations of the anti-trust laws where the threatened loss or damage is the proximate result of the violations, and the cause of action, or the right to sue is not dependent upon any relationship, contractual or otherwise, between the claimant and the offender because these statutes giving relief do not confine their protection "to consumers, or to purchasers, or to competitors, or to sellers. Nor does it immunize the outlawed acts of any of them. The Act is comprehensive in its terms and coverage, protecting all who are made victims of the forbidden practices by whomever they may be perpetrated." *Mandeville Island Farms, Inc.* v. *American Crystal Sugar Company*, 334 U.S. 219, 236, and cases cited. To the same extent is section 26, Title 15, U.S.C.

2. The respondent private corporations and individuals acting with public officials under color of law in this alleged criminal conspiracy violating the anti-trust laws are subject to the restraints of the Civil Rights Acts.

It has long been well settled by this Court that the conduct of private persons and private corporations is subject to the prohibitions of the Fourteenth Amendment when

a State, through its officers, "has so far insinuated itself into a position of interdependence * * * that it must be recognized as a joint participant in the challenged activity." *Burton* v. *Wilmington Parking Authority*, 365 U.S. 715, 725.

And that "private persons, jointly engaged with State officials in a prohibited action, are acting 'under color' of law for the purposes of the State. It is enough that he is wilfull participant in the joint activity with the State or its agents." *United States* v. *Price*, 383 U.S. 787. The participation of the respondents Dr. George D. Stoddard, president of the State University of Illinois, and Dr. Warren G. Cole, Dr. Danley Slaughter, and Dr. Virginia Pierce, all officers or agents of the State University of Illinois, a State Institution, bring the entire conspiracy within the prohibitions of the Fourteenth Amendment and the Civil Rights Act because those corporations and private individuals who took advantage of participation by State officers must suffer the consequences of that participation. "They were participants in official lawlessness, acting in Wilfull concert with State officers and hence under color of law." *United States* v. *Price*, 383 U.S. 787. The language of sections 1983-1985, Title 42, U.S.C. embraces "*all* of the rights and privileges secured to citizens by *all* of the Constitution and *all* of the laws of the United States." *ibid.* This includes the Sherman Anti-Trust Act.

3. The American Medical Association is subject to the Fourteenth Amendment, and therefore to the restraints of the Sherman Anti-Trust Act, when it conducts an illegal conspiracy such as that alleged.

The preconditions for the application of the prohibitions of the Fourteenth Amendment is so far as the American Medical Association is concerned are two: (1) The undeniable fact that this Association is a creature of the State of Illinois, and (2) that this corporation is vested with sufficient economic power and influence concentrated in the State-created vehicle to invade the rights and privileges secured by the Constitution and laws of the United States of 200,000,000 Americans to a material degree. It is sufficient that the manifestations of this concentrated power and the influence which goes with it, as a practical matter, have a significant influence over the lives of a great number of the American People, either nationally, or in a State, City, or even in a small town. *Marsh* v. *Alabama*, 326 U.S. 51; Fruend, *Individual and Commonwealth Thought of Mr. Justice Jackson*, 8 Stan. L. Rev. 6; Lewis, *The Meaning of State Action*, 60 Col. L. Rev. 1083, 1122; *Hawkins* v. *North Carolina Dental Society*, 355 F. 2d 718. The vice stems from power. It is of no significance whether this power derives its source from the ownership of property, from control of professional services which the people require as a whole, or control of particular products or services. The American Medical Association has such power. It has absolute control by statute, formal rule or formal policy or informal policy, over state medical schools and examining boards which provide the only consideration of graduates of schools approved by it or the American Association of Medical Colleges whose lists are identical, and had substantial control over both the number of medical schools in the United States and the rate of production of doctors. As a practical matter, expulsion from this Association is the equivalent to the suspension of a license to practice medicine. Hyde and Wolff, *The American Medical Association, Power, Purpose, and Poli-*

*tics in Organized Medicine,* 63 Yale L. Jour. 969; Kessel, *History and Development of the Medical Monopoly,* Journal of Law and Economics, Vol. 1, October 1958, University of Chicago Law School, pp. 25-29. Even in the absence of direct State Action and participation in the conspiracy by officials of the State University of Illinois, the participation in the conspiracy by the American Medical Association brings the case within the prohibitions of the Fourteenth Amendment and Civil Rights Act, sections 1983-1985, Title 42, U.S.C. The business conducted by the American Medical Association is so necessarily entwined with government policies, and so impregnated with a government character "as to become subject to the constitutional limitations placed upon State Action." *Evans* v. *Newton,* 382 U.S. 296; *Terry* v. *Adams,* 345 U.S. 461.

4. The Respondent, the American Cancer Society, is also subject to the Fourteenth Amendment and therefore to the restraints of the Sherman Anti-Trust Act.

A New York State-created corporation such as the American Cancer Society with its nation-wide affiliates of the same name who submit 40 percent of their gross income to the parent Society, and this corporation having dominant control of cancer research in the United States, and therefore vast power and influence over the lives of a great many Americans afflicted with cancer, is subject to the prohibitions of the Fourteenth Amendment. What makes this more so is the fact that the corporation's entire income is derived from grants-in-aid from both Federal and State Governments, and contributions which are tax exempt and tax deductible donations. Like the American Medical Association, the conduct of the American Cancer Society is also so entwined with government policies, and so impregnated with a government character,

and its existence only possible through such funds from the pockets of the taxpayer, as to become also subject to the constitutional limitations placed on State action. *Evans* v. *Newton*, 382 U.S. 296; *Hawkins* v. *North Carolina Dental Society*, 355 F. 2d 718; Restatement (Second) Trusts, section 368 (1959); 4 Scott on Trusts, section 368, at 2629-2630 (2d ed. 1956); Bogart on Trusts, section 378 (2d ed. 1964); Lewis, The Meaning of State Action, 60 Col. L. Rev. 1083, 1092.

5. The American Medical Association is violating the legal and social sanction of its "monopoly in the trade of medicine" by joining in the alleged conspiracy under which it is perverting such monopolistic power to its own ends at the expense of humanity in general, and these Petitioners in particular.

The respondents admit the allegations in the complaint as to the violations of the Sherman Act, the Civil Rights Act, and the Constitution. These allegations were briefly outlined by counsel for the Board of Trustees of the University of Illinois on May 13, 1966 in the District Court (Vol. II, p. 504 R.) as follows:

> "This pleading which is before your Honor this morning accuses my client, the board of trustees of the University of Illinois, of participating in a criminal conspiracy which Mr. Hyde has gratuitously alleged is an established fact. It accuses all the defendants of forgery, fraud, a conspiracy to take economic advantage of sick people; it asserts that the conspiracy against Krebiozen is calculated and designed solely to perpetuate radiation treatment and surgery as the most expensive means of treating cancer."

The sole defense to the allegations charging a conspiracy appealed to for its justification, is an interpretation and enforcement of section 355(i), now section 505(i), Title

21, U.S.C. This is a statute which authorized the Secretary of Health, Education, and Welfare to promulgate regulations for drugs used solely for investigational use which come within the provisions of the Federal Food, Drug, and Cosmetic Act. This fictional defense was injected into the picture through an amendment of section 505(i) which became effective in June 1963. By this time the admitted conspiracy had endured for 13 years since 1950. The fiction was not available during this period because Krebiozen was being distributed interstate to licensed physicians for use in scientific and experimental research without question, and the sole restraint against such distribution arose exclusively from the conspiracy alleged. The Government did not seek, and has not sought, any injunctive sanctions against interstate distribution at any time during the past 17 years. However, even were Krebiozen prohibited interstate distribution by law or injunction in pursuance of such law, it has been well settled by the higher appellate courts and this Court that in an action arising from violations of the Sherman Act, or the Civil Rights Act, matters not affecting the respondents' responsibility such as the interpretation or enforcement of law cannot be set up as a defense against such violations. This was made clear in *American Medical Association* v. *United States*, 130 F. 2d 233, 246, affirmed 317 U.S. 519, where strikingly similar conspiratorial conduct was conducted by the American Medical Association in order to destroy Group Health in Washington, D.C. There it was said:

> "The licensed monopolies which professions enjoy constitute, in themselves, severe restraints upon competition. But they are restraints which depend upon capacity and training, not special privilege. Neither do they justify concerted criminal action to prevent the people from developing new methods of serving their needs. • • •

"* * * But they have no license to commit crime. When they go so far as to impose unreasonable restraints, they become subject to the prohibition of the Sherman Act. * * *

"Neither can justification for the commission of a crime be found in the fact that its commission benefited the community; and evidence offered for such a purpose is properly excluded. Nor is the fact that a crime was committed with the intent to accomplish some ultimate good, an excuse for its commission; *even if it was for the purpose of enforcing the law.*

"* * * And the same rule applies in cases of conspiracy under the Sherman Act. Neither the fact that the conspiracy may be intended to promote the public welfare, or that of the industry, nor the fact that it is designed to eliminate unfair, fraudulent and unlawful practices, is sufficient to avoid the penalties of the Sherman Act."

The sole defense in this case, like that in *United States* v. *American Medical Association,* 110 F. 2d 703, certiorari denied, 310 U.S. 644, is factual. As the Court said in that case:

"* * *we repeat, that the charge made here, and for the purposes of the demurrer admitted, is that the societies sought to restrain an association of persons of modest means from receiving medical services at lower cost and to coerce doctors and hospital to this end. The charge may be wholly unwarranted and the facts, when they are disclosed on the trial, may show an entirely different state of affairs, but for present purposes, we must take the charge as though its verity were established; and in that light, it seems to us clear that the offense is within the condemnation of the statute. It certainly cannot be doubted that Congress intended to exert its full power, in the public interest, to set free from unreasonable obstruction the exercise of those rights and privileges which are a part of our constitutional inheritance, * * * and any

undue restraint upon them is wrong and is immediate and unreasonable and, therefore, within the purview of the Sherman Act. (Cases cited).

As stated by the Court of Appeals in this case:

"Plaintiffs contend, however, that as long as this conspiracy remains unenjoined, it is immaterial whether or not Krebiozen is exempt from Government regulation. In their complaint, plaintiffs have alleged, in effect, that the F.D.A. has systematically attempted to discredit Krebiozen and to prevent its introduction into commerce."

The same would be true with respect to the Department of Biologic Standards if application for interstate distribution of Krebiozen under the Public Health Service Act is made for purposes of sale, barter and exchange.

However, even if approval is granted for interstate commercial distribution of Krebiozen, so long as the conspiracy remains unenjoined the respondents will effectively prevent its general availability to the suffering public through the continuing reference to the medical profession of the past and of the future fraudulent and misleading publications denying its efficacy, and through continuing professional and economic disciplining of all physicians, hospitals and clinics daring to use it.

6, 7, 8. The sole defense of the Respondents that the statutory procedure under the Federal Food, Drug and Cosmetic Act must be first exhausted is invalid since Krebiozen comes instead under the Public Health Service Act and since it is immaterial whether or not Krebiozen comes under either Act so long as the alleged conspiracy prevents their proper legal implementation.

As correctly stated in the opinion of the District Court on July 18, 1966 (Vol. II, p. 532, R.):

> "The prayer for relief seeks an order enjoining the defendants 'from impeding, hindering, or impairing the free *uncommercial* flow of Krebiozen interstate * * * to the physicians of the plaintiffs * * * for the purpose of continuing experimentation on the plaintiffs by their doctors.'"

The District Court then went on to write (Vol. II, pp. 532-534, R.):

> "Krebiozen is a 'new drug'; introduction of new drugs into interstate commerce is governed by 21, U.S.C. section 355, subsection (a) of which provides as follows:
>
> > "'No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.'
>
> "Subsection (b) provides for a detailed application, including reports of tests made of the drug, a statement of the composition of the drug, a description of the methods and conditions of manufacture, and samples of the drug if requested. The application by a person who wishes to 'introduce or deliver for introduction into interstate commerce' the drug in question."

The District Court was correct in the first instance that what was sought was relief from restraining "uncommercial" flow of Krebiozen interstate for use in scientific and experimental research. Then it strayed far afield from the subject, and in grevious error because Krebiozen is *not* a "new drug", and is *"not"* governed by 21 U.S.C. or any other provision of the Federal Food, Drug, and

Cosmetic Act. This has been determined on three different occasions by the Department of Health, Education, and Welfare, and any application "filed pursuant to subsection (b) of this section" would be futile and has been futile.

What is classified as a "new drug" under the Federal Food, Drug, and Cosmetic Act, is not within the jurisdiction of the courts or the Attorney General to decide. This comes within the jurisdiction of the scientific expertise of the Department of Health, Education, and Welfare to determine. In mid-March 1954, the sponsors of Krebiozen did file an application with the Department of Health, Education, and Welfare under subsection (b), section 355, Title 21 U.S.C. On May 25, 1954 the application was rejected and refused, not on the merits, but because the Department of Health, Education, and Welfare ruled as follows:

> "* * * it is the considered view of the Department of Health, Education, and Welfare that Krebiozen is subject to the Virus, Serum, Toxin provisions of the Public Health Service Act of July 1944, and that the article may not be legally marketed in interstate commerce until licensed under the provisions of that Act.
>
> "* * * *When a license is issued by that unit of the Department, an effective new drug application under the Federal Food, Drug, and Cosmetic Act is not required.*
>
> *"Even if a new drug application became effective for the article, it would still be necessary that it be licensed under the provisions of the Public Health Service Act in order that it be distributed in interstate commerce.*
>
> *"Nothing is to be gained by considering the product as a new drug under the Food, Drug, and Cosmetic Act. It is therefore our suggestion that you take ap-*

*propriate steps looking toward the issuance of a license for the article by the Laboratory of Biologics Control.''*

Immediately after the determination of the Department of Health, Education, and Welfare of May 25, 1954, the sponsors of Krebiozen submitted additional data to the Department of Health, Education, and Welfare in an effort to show that Krebiozen did come within the provisions of the Federal Food, Drug, and Cosmetic Act. This, again, was rejected on August 12, 1954 as follows:

"Our scientists, on the information submitted, classify this drug as an 'analogous product' within the meaning of the Public Health Service Act.

"Since the drug, in the Department's view, may not be distributed for *barter or sale* unless produced in a licensed establishment, we recommended to you in our letter of May 25, that you take the problem up with the Laboratory of Biologics Control *rather than pressing for an effective new drug application.* The Department can hardly construe the two laws [illegible] that one stituent would apparently approve interstate distribution of a drug by permitting a new drug application to become effective while the more directly concerned constituent regarded the distribution as a contravention of the law enforced by it.

*"We do not insist on the needless duplication of satisfying the requirement of both laws.* We do insist, however, that products subject to license control meet the requirements of the Public Health Service Act. When they do, safety is assured and *a new drug application is not necessary.*

*"We renew our recommendation that you take steps to obtain a license rather than making further efforts to complete the new drug application.''*

The efforts of the sponsors of Krebiozen to have the article classified as a product coming within the provisions of the Federal Food, Drug, and Cosmetic Act were practical because in 1954 up to 1963 all that was required to put a drug into interstate commerce was that the drug was safe. On the other hand, to put drugs into interstate commerce which came within the provisions of the Public Health Service Act, both safety and effectiveness were required. At this time, under neither law was there any restriction as to interstate distribution of drugs for use in scientific and experimental research and which were not for sale, barter, or exchange. There is still no restriction for such distribution under the provisions of the Public Health Service Act under which Krebiozen comes. Again, in 1961, the sponsors of Krebiozen made another effort to have Krebiozen classified as a "new drug" under the provisions of the Federal Food, Drug, and Cosmetic Act by submitting additional data as to its components, and again the application was rejected on the same grounds as follows:

> "Until data are submitted convincingly demonstrating that Krebiozen is a hormone within the meaning of the Public Health Service Regulations the article will be regarded as subject to the licensing provisions of the Public Health Service Act. *When it is licensed an effective new drug application is not required.* The article cannot be legally marketed in interstate commerce until it is licensed under the Public Health Service Act.
>
> *"We recommend that you abandon the idea of pursuing an effective new drug application and submit an appropriate application for licensing of Krebiozen by the Division of Biological Standards, National Institutes of Health, U.S. Public Health Service."* (all underscoring supplied)

The latter determination by the Department of Health, Education, and Welfare was rendered on June 9, 1961. (For rejections in 1954, see pp. 151-154, Vol. III, Record).

What has happened in this case is simple. The respondents know the allegations in the Complaint are true, and they know that the facts alleged and provable constitute serious violations of the Sherman Act and the Civil Rights statutes. They also know that cancer is widespread among the under-privileged, the class that can least afford the luxury of present expensive surgery, hospitalization, narcotics, radiation therapy and similar orthodox, and admittedly largely ineffective, treatment—the class that will be most benefitted by an inexpensive non-toxic treatment such as Krebiozen. The Court of Appeals clearly recognized this when it characterized this suit as follows:

> " * * * the complaint is an outcry of hopeless, suffering cancer victims who lack the funds required by the recognized cancer therapies, and who believe in the ameliorative and curative properties of the now well publicized drug, Krebiozen."

In an attempt to avoid answering these allegations, they admit them, but seek immunization from the violations by relying on a defense based on the proposition that the determinations of the Department of Health, Education, and Welfare in 1954 and 1961 were erroneous, and for this reason they claim the right to conduct such a conspiracy in order to enforce what they claim is the law. For the first time in the judicial history the courts below have sustained such a claim, and even went further that this defense operates retroactively for over 13 years prior to the enactment of the law relied on. Such a defense, of course, is not available. *American Medical Association*

v. *United States,* 130 F. 2d 233, 246, affirmed, 317 U.S. 519. Moreover, if it be held by this Court that the determinations of the scientific expertise of the Department of Health, Education, and Welfare in 1954 and 1961 were in error—and such a possibility is impossible to imagine—and that Krebiozen does come within the provisions of the Federal Food, Drug, and Cosmetic Act, then the respondents and the Courts are caught with no choice but between the rock and the whirlpool, because if it be held that this article does come within the provisions of the Federal Food, Drug, and Cosmetic Act, then the applications made under subsection (b), 355, Title 21, U.S.C. in 1954 and in 1961 became effective under section 355 (c) because they were not denied on the merits within the time made mandatory by that subsection which, under the law as it stood at the time, the article was already in interstate commerce by default. Subsection 355 (c) in 1954 and 1961, provided as follows:

> *"Effective date of application*
>
> *"(c) An application provided for in subsection (b) of this section shall become effective on the sixtieth day after the filing thereof, unless prior to that day the Secretary by notice to the applicant in writing postpones the effective date of the application* (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application."

It is all around conceded that the application was not denied on the merits within the 60-day limitation provided by section 355(c), nor was there any extension of time beyond this limit taken by the Secretary, nor was such mandatory notice given to the applicant prior to the sixtieth day of its filing, nor was there any "notice to the applicant in writing" that further time was required by the Secretary to "investigate the application." Instead

of holding that Krebiozen is subject to that Act and accordingly complying with the statutory permissible action within the now passed statutory time limit, the Secretary in each instance, as set forth above, ruled that the Act itself does not apply to Krebiozen.

9. Krebiozen being subject only to the Public Health Service Act can be freely distributed interstate so long as not for sale, barter, or exchange, without Federal approval.

All articles which are governed by the Public Health Service Act may be legally distributed interstate for "use in scientific and experimental research" so long as they are not for "sale, barter, or exchange." Section 262, Title 42, U.S.C. prescribes the requirements for putting these articles into interstate commerce. The statute is penal, and is directed against persons who send, carry, or bring into the United States, or from one state to another, articles which come under the provisions of the statute, for "sale, barter, or exchange" and against such persons only. Being a penal statute, the natural meaning of the words "sale, barter, or exchange", defining the offense and the class of offenders cannot be enlarged by construction because of any underlying intent. These words contain no ambiguity whatever. This has always been rigidly adhered to by this Court. *United States* v. *Wiltberger,* 5 Wheat. 76, 95; *Sturges* v. *Crowinshield,* 4 Wheat. 122, 202; *Lake County* v. *Rollins,* 130 U.S. 662, 670; *United States* v. *Baltimore and Ohio Southwestern Railroad Company,* 222 U.S. 8. That has been the construction given to this particular penal statute by the Attorney General for over 50 years. 29 Opinion of Attorney General 340. Krebiozen as it does, coming within the provisions of the Public Health Service Act is not prohibited from interstate distribution for "use in scientific and experimental research."

10. The regulations authorized under the Federal Food, Drug and Cosmetic Act cannot be engrafted on the Public Health Service Act so as to govern Krebiozen as an "analogous" product, not subject to the former Act, but instead to the latter Act.

Congress in granting the secretary of Health, Education, and Welfare the authority to promulgate regulations by the amendment of section 355(i), Title 21, U.S.C. neither explicitly or by implication authorized that such regulations should be extended to articles governed by the Public Health Service Act. On the contrary, the grant is expressly limited to drugs solely for investigational use which come within the provisions of the subsections (a) to (h) foregoing subsection (i), and this is further made clear that the regulations are for the explicit purpose which "will enable him (the Secretary) to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section." Krebiozen does not come within the subsections of section 355, Title 21, U.S.C. foregoing subsection (i), and as pointed out in the previous paragraphs there can be no "event of the filing of an application pursuant to subsection (b) of this section." To add regulations to a statue under the Public Health Service Act which Congress did not think necessary to prescribe would not be regulation, but legislation. The object sought by the respondents or even by the Secretary of Health, Education, and Welfare can only be accomplished by an amendment to the statutes of the Public Health Service Act. This is not the office of the respondents, or the Secretary of Health, Education, and Welfare. *Morrell* v. *Jones,* 106 U.S. 466; *United States* v. *United Verde Copper Company,* 196 U.S. 207; *United States* v. *Standard Brewery,* 251 U.S. 210.

11, 12. Insofar as the Federal Food, Drug and Cosmetic or any other Federal Act can be applied to inhibit the practice of medicine, the control of which is exclusively in the States, such an Act is unconstitutional.

No intelligent student of law, or any Justice of this Court, will deny that the practice of medicine comes exclusively within the powers reserved by the States, and is guaranteed against infringement by any agency of the Federal Government through the Tenth Amendment, and to the same extent, that the Fourteenth Amendment guarantees all of the rights and privileges secured by all of the Constitution and all of laws of the United States against State infringement. *United States* v. *Price*, 383 U.S. 787. That the practice of medicine is exclusively a State right, does not lessen its importance. Few will deny that it is the inherent and pre-constitutional right of the people to have the benefits of the services of the medical doctor. If the laws of the States are in violation of the rights guaranteed by the Fourteenth Amendment, they are void. To the same extent, if a federal law infringes on the rights reserved by the States they are also void under the Tenth Amendment. And if either a State or Federal law violates the inherent rights reserved by the people by the Ninth Amendment it is void. Section 355(i), Title 21, U.S.C., under the construction given it by the respondents would be such an invalid law because it infringes on the rights of doctors to practice their calling, and the inherent rights of the people to have the benefits of this medical science. If the construction of the respondents is sustained, then Congress has, under the pretext of the Commerce Clause, passed a law for the accomplishment of an object not intrusted to the Federal Government, as the practice of medicine is not naturally and reasonably

adapted to the effective use of that power, because this is a power exclusively within the power reserved for the States. This has long ago been settled by this Court. *Linder* v. *United States*, 268 U.S. 5.

Under the Constitution, doctors of medicine, must by the very nature of their profession in the preservation of life, have free and immediate access to medical remedies, orthodox or unorthodox, where in their opinion such remedies might save or prolong the lives of their patients. To ascertain the limited or the unlimited function of the doctor in the area of doctor-patient relationship, we must search in the laws of the State, because the Federal law can have no application or any impact on this profession. To the extent that it would have, the law would be unconstitutional.

Undoubtedly, the Federal Government can enact laws or authorize the promulgation of regulations, and prescribe certain conditions when it is sought to introduce into interstate commerce and drug, and its effect on such commerce, or even to its safety. Through its health agencies it could make suggestions as to the efficacy of such drug in treating a particular disease. But in the final analysis this efficacy is exclusively within the judgment of the doctor administering the proposed remedy. This is so because the efficacy of the remedy is not a matter of fact, but merely an opinion, and not the opinion of any particular school of medicine, but of the doctor administering it. The different schools of medicine have their followers, and many who believe in one will pronounce the other wholly devoid of merit. However, "there is no precise standard by which to measure the claims of either, for people do recover who are treated according to the one or the other school. * * * It is a question of opinion in

all of the cases, * * * yet after all it is in each case opinion only, and not existing facts with which these cases deal." *School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94, 103-104. Probably the best example of this can be found in *Stammer* v. *Board of Regents*, 262 A.D. 372, affirmed 287 N.Y. 359. There a doctor effected a cure for cancer when the approved and so-called orthodox methods of treatment had proved futile, and he was punished for it. What the State law is on the practice of medicine was clearly outlined in that case, and the ruling on that case and similar State cases is binding on the Federal Government. It was held that any restrictions which stifle initiative and originality on a doctor in the practice of medicine already skilled in the medical art, in attempting new methods of saving a life, especially when undertaken with the patient's full knowledge and consent, and on a strictly patient-doctor relationship, and not for experiment for the sake of experiment, but an attempt to prevent death, or prolong a life, when all known and so-called orthodox methods of treatment have failed, and when the patient's very life had been despaired of, such restrictions are unlawful. It is equally unlawful against the Federal Government where it imposes the restrictions.

The wrong is all the more aggravated when this stifling of initiative and originality in the "Progress of Science and the useful arts" is the result of a criminal conspiracy conducted by two corporations, a State University, and a series of individuals, in violation of the Sherman Act as the facts in the instant case reveal, and violates Article 1, section 8, of the Constitution concerning the "Progress of Science and the useful arts", and the Fifth, Ninth, Tenth, and Fourteenth Amendments of the Constitution. This question of such immense social significance, standing alone, warrants review on certiorari by this Court because

this is a class action in behalf of over 300,000 Americans, who, according to statistics, will die within the next year, not only with cancer but from cancer.

13. The District Court was in error when it ruled that Krebiozen came within the provisions of the Federal Food, Drug, and Cosmetic Act. In its opinion on July 18, 1966 (Vol. II, p. 534, R.) it wrote:

> "Plaintiffs claim that Krebiozen's sponsors need not invoke the remedy provided by Congress. However, it is too well settled to require extended discussion that where Congress creates an expert administrative agency to perform a specific regulatory task which requires expertise, the agency cannot be bypassed. All matters properly within the agency's scope of authority must be referred to this agency for action in the first instance."

We have no quarrel with the determinations of the Department of Health, Education, and Welfare. On the contrary we have prayed that they be enforced and obeyed, and have asked the courts to sustain them, and make its judgment in accordance with them: that Krebiozen comes within the provisions of the Public Health Service Act, because as determined by the Department of Health, Education, and Welfare nothing is to be gained by an application under the Federal Food, Drug, and Cosmetic Act, and coming as it does, under the Public Health Service Act, it may be distributed interstate for "use in scientific and experimental research" when not for "sale, barter, or exchange." Section 262, Title 42, U.S.C.; 29 Opinion of Attorney General 340. It is the respondents that challenge the determination of the Department of Health, Education, and Welfare, not the petitioners. They use this as a flimsy defense to justify a conspiracy in violation of the antitrust laws. Then the District Court went on to write in the next paragraph:

"This rule applies to Krebiozen, even though the complaint in this case is framed in terms of the civil rights and the anti-trust statutes. Clearly, until an invocation of the provisions of section 355 has proved fruitless, there is no possible equitable relief that can be granted that does not directly interfere with the FDA's jurisdiction. Whatever injury plaintiffs presently suffer as a result of restrictions on interstate distribution of Krebiozen is the result of the operation of the Food, Drug and Cosmetic Act, *and not of illegal activity by the defendants.*" (emphasis supplied)

Both the District Court and the Court of Appeals rely on *Turkel* v. *Food and Drug Administration*, 334 F. 2d 844. To one versed only in the English language this is very difficult to comprehend as under the determinations of the scientific expertise of the Department of Health, Education, and Welfare concerning both Krebiozen and Dr. Turkel's "U" Series drug, there can no more be a valid license issued for "U" Series under the provisions of section 262, Title 42, U.S.C., than there can be an effective application for Krebiozen under section 355 (b), Title 21, U.S.C., the Federal Food, Drug, and Cosmetic Act. It is as simple as that. Nor can there be a valid indictment or injunction sanction for a violation of section 262, Title 42, U.S.C. where the "U" Series drug is concerned, any more than there can be a valid indictment or injunction sanction for a violation of section 355 (b), Title 21, U.S.C. of the Federal Food, Drug, and Cosmetic Act, where Krebiozen is concerned. The indictment found against the sponsors of Krebiozen under the Federal Food, Drug, and Cosmetic Act in 1964, which culminated in a verdict of "not guilty" was not worth the paper it was written on. If there was a violation at all, it was under section 262, Title 42, U.S.C. It was held in Turkel, that a direct appeal

to the United States Court of Appeal could have been perfected had Dr. Turkel been denied an effective application under section 355 (b), Title 21, U.S.C. As to Krebiozen, the Department of Health, Education, and Welfare has held on three occasions that there can be no valid "event of the filing of an application pursuant to subsection (b) of this section." This should completely rule out the *Turkel* Case as authority for use in the present litigation.

14, 15. That the questions of irreparable damage and loss to the liberty and lives of the petitioners were raised at all on February 4, 1967, and May 13, 1967 was sufficient on which to grant a hearing and make findings of fact and conclusions of law under Rule 52, of the Federal Rules of Civil Procedure. It is elementary in law that premature expressions by the District Court predicting the ultimate and, in fact, the inevitable disposition of the case rendered as to the issue before it, or any issue on the merits useless. The District Court determined right there and then such disposition, and all the Court's subsequent actions were made with the already predetermined disposition as the goal. These premature expressions are that "Cancer sufferers should have no illusory hope that any legal action involving Krebiozen can provide them with the relief they seek, for those hopes are almost certain to be destroyed in frustration.

The only credible hope, course of hope, is through the FDA, and, if necessary, the system of careful review of FDA action. That is the only route by which Krebiozen has a chance at all of being freed from the present bans imposed upon it.

This lawsuit, and all lawsuits like it, are doomed to failure." (Vol. II, p. 365, R.) In the first instance, as pointed out before, there can be no FDA action, and no "system

of careful review of FDA action." That has been determined by the Department of Health, Education, and Welfare. It is elementary in law that the opinion delivered from the bench cannot substitute for the special, formal, and mandatory findings by which it is the duty of the Court appropriately and specifically to determine the issues before it, and such issues to be determined on these particular applications concerned the confiscation of life. In such a case the plaintiffs had a plenary right to have a factual showing on the probable confiscatory effect of the alleged criminal conspiracy of that life, and be allowed to demonstrate by competent legal evidence the propriety in the interest of justice, and in order to prevent continued irreparable injury to life until a final hearing on the merits could be had. This is in conformity with the long standing and salutary principle that essential facts should be determined before passing on the grave constitutional, Civil Rights, and other rights in this case and the alleged violation thereof. *Polk Company* v. *Glover,* 305 U.S. 5; *Borden's Farm Products* v. *Baldwin,* 293 U.S. 194; *Mayo* v. *Lakeland Highlands Canning Company,* 309 U.S. 310; *Railroad Commission* v. *Maxcy,* 281 U.S. 82. Observations expressed in an opinion not based on facts are not such findings.

16. The inherent right to survival guaranteed by the Fifth, Ninth and Fourteenth Amendments includes the right of an individual to access to a non-toxic remedy of his own free choice which he himself judges to be indispensible for his life.

The right to freedom of survival is the primary right upon which all other rights depend: unless one survives all other rights are of no value and without use.

The American Medical Association in concert with the other respondents have now conducted for over fifteen years a studied course of action and effective propaganda to destroy a medical remedy for cancer, which is non-toxic, effective and would be inexpensive—a remedy that obviates surgery, extensive hospitalization, narcotics, and radiotherapy. But, therefore, it will eliminate the vast income presently received by the medical establishment derived from such orthodox treatment. Krebiozen inevitably confronts the medical establishment with the choice of promoting and definitely testing this independently discovered non-toxic remedy to the detriment of its economic interests and prestige of discovery, or to hinder its development and to destroy it in order to protect such interests. As in similar instances of independent discovery in the past, it has chosen the latter course. As a direct result of this conspiracy the major portion of some 300,000 victims of cancer have now needlessly died each year during this conspiracy, an unnecessary sacrifice in human life in the aggregate so great as to be difficult to comprehend or entertain.

If the decisions of the District Court and the Appellate Court are not reversed by this Court it will now be established in this country that in medical matters the American Medical Association is in fact and practice immune to suit of private individuals and, as to them, supreme and even superior to the Government, the Courts, and the Constitution.

17. The Federal Food, Drug and Cosmetic Act by reason of its statutory permissible delay of approval thereunder and of further extended delay in administrative and thereafter judicial appeals violates the rights

of the petitioners and others, to whom such delays are fatal, under the Fifth, Ninth and Fourteenth Amendments.

The Amendment of 1961 to the Federal Food, Drug and Cosmetic Act known as the "Kefauver Amendment" added the requirement of proof of effectiveness of a new drug to the satisfaction of the personnel staffing the Food and Drug Administration before access to such a medical remedy could be available to patients, otherwise declared hopeless, whose survival depends upon such a remedy. Prior to an application for an approval it is necessary to obtain and assemble, at an expense usually beyond reach, of private individuals and independent researchers, such voluminous and technical scientific production and clinical data as these employees may insist upon, as a precondition for their consideration of the effectiveness of a new drug. If such personnel choose capriciously or arbitrarily to deny such investigational exemption there is no right of judicial appeal: *Turkel* v. *F. D. A.*, 6 Cir. 334 F. 2d 844 (1964). Furthermore, if and when an application is made directly for approval of interstate commerce distribution the Secretary of Health, Education and Welfare can, under that Amendment, delay for more than half a year, after the application is made before approving it: 21 U.S.C.A. 355(c).

If he capriciously or arbitrarily refuses approval, resort must first be had by the applicant to administrative appeals and only thereafter to the Courts for judicial appeal: 21 U.S.C.A., section 355(h).

In the meantime, as would happen in the case of Krebiozen, were it a new drug and therefore subject to that Act, those whose lives exclusively depend upon access to such new drug have long since, painfully expired. Any eventual success on appeal is for them but a pyrrhic victory.

The Act as thus amended therefore clearly violates the right to survival of such unfortunate and forgotten victims. As to them this Act is clearly, unconstitutional and fatally defective because not providing for temporary exception and relief prior to approval to all whose survival uniquely depends upon a new drug.

The District Court and the Court of Appeals in this case have now established, if their decisions are not reversed by this Court, that this fatal gap will not even be cured by judicial relief in the form of a temporary injunction.

Had the Kefauver Amendment provided instead that a sponsor of a new drug could not represent to the public that it is effective, until such effectiveness was approved by the Food and Drug Administration, and prior to that time must represent that such recognition of effectiveness had not been yet obtained, then it would have accomplished the salutary objective of preventing the foisting on the public of new drugs represented to be effective when in fact not proved effective—without, however, having subjected the basic right of free choice of a physician or a patient of an indispensable medical remedy to possible fatal restriction and delay.

Krebiozen is a glaring illustration as to how the power of Governmental control under such a statute can be exercised, not for the good of the public, primarily, but instead for the benefit of the economic and prestige interests of the American Medical Association, in the case of any new fundamental, independently developed medical remedy that may conflict with its interests.

## SUMMARY

To fully understand this case the position of the American Medical Association as *respondeat superior* must be observed as a stark realism. This Association conjointly with and through the other respondents, have endeavored for seventeen years to destroy the independently developed non-toxic, anti-cancer therapy, Krebiozen. This they admit. The purpose is to preserve the monopoly alleged because if this therapy was introduced into medicine, and it proved effective in the treatment of cancer, it would render obsolete the major portion of current surgery, radiation, chemotherapy, narcotics, long and expensive hospital and nursing care. It has successfully prevented its adoption through fraudulent publications in authoritive medical journals under its control, through suppression of voluminous scientific reports evidencing its effectiveness in the control of cancer, through thwarting any definitive scientific clinical tests, and through economically and professionally disciplining all physicians, clinics and hospitals daring to investigate it.

Both the courts below have now, in the instant case, denied the present application. They have effectively prevented the exposure and proof of this illegal course of conduct by the American Medical Association which, if sustained by this Court will destroy all independent research on cancer. If the petitioners are heard, this would establish the validity and availability of this therapy which could save the lives of 300,000 Americans destined to die from cancer within the next year because the American Medical Association must preserve the monopoly on therapies which are profitable and at the same time ineffective in the treatment of the disease.

In so doing the courts below have failed or refused to recognize, or where so recognizing them, have refuted, without a hearing of the facts, the allegations of these unfortunate citizens. They have dismissed their application made under the law where "Any person, * * * may sue for and have injunctive relief from threatened loss or damage by violation of the antitrust laws." (Section 26, Title 15, U.S.C.). These courts have instead, dismissed the application of these petitioners and in complete disregard of their constitutional rights. In so doing they have furthered the extension of control of the American Medical Association and authorized that criminal conspiracy is a valid weapon to enforce law. Under such ruling the monopolistic control held by the American Medical Association has not only become more effective, but validated.

If the decision of the courts below is not reversed the abolition of civil rights will be an established fact sanctioned by the judiciary in so far as medical remedies are concerned. It will have established that we are now all the virtual slaves of this Combination in so far as our health is concerned.

It is now common knowledge that independently discovered and developed market advances in medical science have been deliberately delayed by this Association for years. It had attempted to destroy Group Health Plans by the same tactics as used in this case. *American Medical Association* v. *United States,* 130 F. 2d 233, affirmed 317 U.S. 519. Numerous other advances in medicine have been falsely labelled as "Quack Remedies" and destroyed. Those which have broken through are merely the top of the iceberg and have little relation to those still under the surface. The Salk vaccine was so branded and delayed for six years and its acceptance finally forced by a group of the laity in the "March of Dimes" under the impetus

of the then President of this Republic. Sabin had to obtain such a body of clinical proof that it could not be gainsaid, by going to another (and, in this respect, scientifically freer) country, the Soviet Union. Penicillin, progenitor of present anti-biotics, discovered by Fleming, a chemist, was derided for more than ten years, and its recognition only finally forced by the Army in the Second World War. The same resistance attended the discoveries, such as "606" by Ehrlich, smallpox vaccination by Jenner, antisepsis in surgery by Holmes, Lister, and Keen, microbes by Pasteur, aberrations by Freud, sanitation in children by Semmelweis, and even circulation of blood by Harvey.

In each and every instance this Association, and before it orthodox medicine as then constituted, resisted such independently developed profound medical advances either because detracting from its prestige, and today thereby jeopardizing justification for continuation of vast research grants, or because threatening obsolescence of current medical practices with attendant temporary economic hardship and readjustment to its members. In all instances the incidental continuation of loss of life or of pain to thousands of sufferers has been given only subordinate consideration.

This present suit represents the first instance where such sufferers as the Petitioners, have themselves raised their voices and applied to the Courts of the land for the elemental right of a judicial hearing in which to substantiate any controverted allegations as to a repetition of this course of conduct by the respondents, in this instance with respect to the independently discovered medical remedy for cancer, Krebiozen. Five of them have died during the attempt. If denial of judicial review of this alleged conspiracy is delayed sufficiently longer the respondents will prevail as the suit will become moot.

The Courts below, however, stand aghast at the thought of such a "frontal attack" against so powerful and "sacred" a combination of these Respondents—and at every step have thwarted any opportunity for a hearing on the facts—even though these petitioners, anticipating such a mistaken reaction, have thoroughly documented their pleadings with verified evidentiary exhibits as prima facie justification of the substantiality of their application.

On the record of this case these petitioners, already given up as "hopeless" by these respondents, now petition this Court to reverse the refusal of the courts below to afford them a hearing, and aver that if such is not granted a denial by this Court will not only be at the expense of their survival and freedom of pain, but at such expense to thousands of other Americans presently suffering from pronounced "incurable" cancer.

## CONCLUSION

For the foregoing reason, on this application, the judgment of the Court of Appeals should be vacated, and the case remanded to the District Court for a hearing on the facts, or in the alternative, the writ of certiorari should be granted and the case put on the docket for primary consideration.

Respectfully submitted,

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Telephone: 215-MI9-0542

APPENDIX A

In the

# United States Court of Appeals

## For the Seventh Circuit

SEPTEMBER TERM, 1967 — APRIL SESSION, 1968

Nos. 15847, 15930

DR. F. ALLEN RUTHERFORD, EDWARD J. CRONLEY, VERA MAE JEFFRIES, DOROTHY WILLIAMS, C. R. EASTER, CHESTER PLONSKI, and SALLY RANICH, *et al.*,

*Appellants,*

vs.

AMERICAN MEDICAL ASSOCIATION, *et al.*,

*Appellees.*

Appeals from the United States District Court for the Northern District of Illinois, Eastern Division.

June 23, 1967

Before HASTINGS, *Chief Judge*, and DUFFY, *Senior Circuit Judge* and SCHNACKENBERG, *Circuit Judge.*

HASTINGS, *Chief Judge.* This is an appeal from the district court's dismissal, on all counts, of plaintiffs' suit for a permanent injunction against defendants, requiring them to cease interfering, in any way, with the national distribution of an alleged cancer drug, Krebiozen.

Jurisdiction in the case was asserted to arise from issues of constitutional import and from the civil rights statutes, 42 U.S.C.A. §§ 1983, 1984, 1985.

Plaintiffs are Dr. Allen Rutherford and a number of cancer patients who have been treated for their disease by the use of Krebiozen.

The mammoth amended complaint — 243 pages, excluding exhibits — which contained eight counts, is difficult to characterize. Most of the complaint is general, irrelevant, vituperative, scandalous and conclusory. Its burden, presumably set down in the hope of establishing a conspiracy of medical and health organizations and institutions, is a full frontal attack on defendants, the American Medical Association, the American Cancer Society, the medical profession generally, the Board of Trustees of the University of Illinois, the Federal Food and Drug Administration (FDA), a number of employees of the foregoing and various individual defendants.

The objective of this attack is to show that the medical profession, with allied parties, purposefully suppresses innovations in medical therapy and that the named defendants have joined in this conspiracy. In essence and sympathetically viewed, the complaint is an outcry of hopeless, suffering cancer victims, who lack the funds required by the recognized cancer therapies and who believe in the ameliorative and curative properties of the now well publicized drug, Krebiozen. Supported by testimonials of Krebiozen's efficacy, they place hope in this drug, but they find it withheld from interstate distribution,[1] and they lay the blame for its unavailability upon the defendants.

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[1] Krebiozen is available within Illinois and may be manufactured and distributed within other states.

Krebiozen is unavailable in interstate commerce. As a new drug, it has not received an approval, required by the Food, Drug and Cosmetic Act, 21 U.S.C.A., § 355,[2] which would permit its introduction into interstate commerce.

Section 355 of the Act establishes an introduction procedure for new drugs, designed to elicit sufficient scientific information about a drug, including reports on investigations, composition, methods and precautions in manufacture, and samples of the drug, which will permit an intelligent assessment of its safety and efficacy. Section 355(i) provides an alternative procedure for drugs intended solely for investigational use. Compliance with a comprehensive set of regulations promulgated by the Secretary of Health, Education and Welfare is required.

Krebiozen has complied with neither procedure. In 1963, a § 355(i) notice was filed, but was quickly withdrawn. Another notice was filed in 1966, but it did not approach compliance with the regulations. As it now stands, Krebiozen has not been approved, exempted, or denied approval under § 355, and no application with respect to Krebiozen is pending before the FDA.

In a previous case of this kind, we held that an essential element of the plaintiff's case is a showing that under the appropriate standards, Krebiozen would be approved or exempted. *Tutoki* v. *Celebrezze*, 7 Cir., 375 F. 2d 105 (1967). Since jurisdiction for judicial review of administrative action is statutory in this case, 21 U.S.C.A. §

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[2] "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug." 21 U.S.C. § 355 (a).

355(h); *cf. A.F.L.* v. *Labor Board,* 308 U.S. 401 (1940), initial approval or exemption of a drug is within the primary jurisdiction of the FDA. *Tutoki, supra.* Only after action by the FDA is court review appropriate and provided for by statute. 21 U.S.C.A. § 355(h). *Cf. Turkel* v. *Food and Drug Administration, Dept. of H., E. & W.,* 6 Cir., 334 F.2d 844 (1964).

Plaintiffs contend, however, that as long as the alleged conspiracy remains unenjoined, it is immaterial whether or not Krebiozen is exempt from Government regulation. In their complaint, plaintiffs have alleged, in effect, that the FDA has systematically attempted to discredit Krebiozen and to prevent its introduction into commerce. It is argued that on a motion to dismiss, we must accept the truth of these allegations.

Accepting their truth arguendo, plaintiffs still have not shown that they have in good faith attempted to comply with the procedures established by Congress for the introduction of new drugs, nor has it been shown that the failure to apply can be attributed solely to the activities of the FDA and the defendants. The fact that compliance might be expensive and burdensome is not unfairness in the procedure, but a consequence of a reasonable Congressional scheme for the introduction of new drugs.

Without an attempted good faith application for approval or exemption, we have no jurisdiction to determine whether the FDA has illegally placed impossible or unreasonable conditions on approval or exemption, or has made requests for information impossible to fulfill, or whether the FDA has been dilatory, biased, or discriminatory. Until someone has attempted to comply with the Act with respect to Krebiozen, plaintiffs' appeal should be to the sponsors of the drug.

Plaintiffs further contend that the Act cannot regulate Krebiozen since, as it is to be distributed free of charge for investigational purposes, it is not in commerce. There is no merit in this argument, for regulation under the Commerce Clause is not limited to articles or activities for which there is a transfer for value. *U. S.* v. *Underwriters Assn.*, 322 U.S. 533 (1944); *Bell* v. *Porter*, 7 Cir., 159 F. 2d 117 (1946), cert. den., 330 U.S. 813 (1947).

Plaintiffs also contend that Krebiozen is exempt from the requirements of the Act because it is non-toxic. This argument is mistaken, for the new drug provisions of the Act, which prohibit introduction of new drugs without approval, apply without reservation to all new drugs. Even if Krebiozen is non-toxic as alleged, toxicity is not the sole criterion to be applied by the FDA to new drugs. Effectiveness of the drug as well as its safety and the safety of its manufacturing procedures is a relevant criterion. 21 U.S.C.A. § 355(d); *cf. United States* v. *Allan Drug Corporation*, 10 Cir., 357 F. 2d 713 (1966).

Plaintiffs argue that Krebiozen is not a drug, but a biological product not falling within the scope of the Food, Drug and Cosmetic Act. If Krebiozen is a biological product, however, it must meet the more stringent licensing provisions of the Public Health Service Act, 42 U.S.C.A. § 262, which it has not done. *Cf.* 21 C.F.R. §§ 130.2(a) and 130.3(g). We do not find a gap between the Food, Drug and Cosmetic Act and the Public Health Service Act which would leave Krebiozen unregulated under either statute.

Finally, we note that plaintiffs, because they have not shown that at least one of the defendants acted under color of state law to injure them or deny them a federally protected right, have not stated a cause of action under

the civil rights statutes. See *Kamsler* v. *M.F.I. Corp.*, 7 Cir., 359 F. 2d 752 (1966). In this case, only the University of Illinois can be considered a state agent. There is no legal requirement that the University of Illinois permit its personnel to experiment with Krebiozen or to endorse it, and plaintiffs have no more right to Krebiozen experimentation at the University of Illinois than they do at any research institution. The law does not require that innovations, good or bad, be investigated or accepted. Since plaintiffs have suffered no legal injury from the University's decision, they have no cause of action under the civil rights statutes.

In view of the various sufficient grounds for upholding the district court's dismissal of plaintiffs' suit, we have not considered questions regarding plaintiffs' standing, venue, or the propriety of the class action under Rule 23, Federal Rules of Civil Procedure.

This case was submitted to this court for decision on May 3, 1967, following the hearing of full oral argument. Subsequently, on June 12, 1967, plaintiffs filed a "Petition for Certification of Six Questions by the United States Court of Appeals for the Seventh Circuit to the United States Supreme Court as Provided by Section 1254, Title 28, U.S.C.A., and Rule 37 of the Rules of the Supreme Court." They further request a stay of any consideration of this appeal until such questions are answered by the Supreme Court.

The first four questions asked are jurisdictional in nature and involve the construction of various federal statutes considered herein, *inter alia*, the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, the Sherman

Antitrust Act and the Federal Civil Rights Act. The fifth and sixth questions concern a determination of whether the American Medical Association and the American Cancer Society are subject to the restrictions and prohibitions contained in the Fourteenth Amendment and the Civil Rights Act.

It appears to be well settled that certification of questions pursuant to 28 U.S.C.A. § 1254 rests in the discretion of this court and cannot be invoked by a party as a matter of right. We respectfully decline to exercise our discretion to certify the questions submitted to the Supreme Court and plaintiffs' motion for certification is now denied. In view of our disposition of this appeal, plaintiffs are left with the right to seek review thereof by petition to the Supreme Court for a writ of certiorari.

For the reasons set out in this opinion, the judgment of the district court dismissing plaintiffs' action for injunctive relief is affirmed.

AFFIRMED.....

A true Copy:
Teste:

.....

*Clerk of the United States Court of Appeals for the Seventh Circuit.*

## APPENDIX B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
Judge's Chambers
*Bernard M. Decker, Judge*
Chicago 60604

July 18, 1966

OPINION OF DISTRICT COURT

Re: *Dr. F. Allen Rutherford, et al.* v.
*The American Medical Association, Inc., etc., et al.* — No. 66 C 7

Gentlemen:

I have considered the complaint, the motions to dismiss and the briefs that have been filed. The motions are granted.

Plaintiffs, a physician and ten victims of cancer, seek a permanent injunction against numerous alleged present obstacles to national distribution and use of Krebiozen, a purported treatment for cancer. Defendants include the American Medical Association ("AMA"), the American Cancer Society ("ACS"), the University of Illinois ("UI"), employees of these three corporate defendants, and numerous individuals. Plaintiffs charge a complex and far-reaching conspiracy among the defendants to prevent the use and success of Krebiozen as a cancer drug by means of varied formal and informal devices; it is this to which the 243-page amended complaint is directed. Jurisdiction is alleged under the Civil Rights statute, 42 U.S.C. sections 1983-1985, the anti-trust laws, 15 U.S.C. section 1, et seq., and the Food, Drug, and Cosmetic Act, 21 U.S.C. sections 301, et seq.

This suit was filed on January 3, 1966; it is similar in most important respects to the suit filed by other plaintiffs on January 8, 1965, which I dismissed on January 25, 1966, for reasons set forth in a letter of opinion. In the present suit, a motion for a temporary injunction was denied on February 4, 1966, in an opinion delivered from the bench. A similar motion was denied on May 13, 1966; denial of the second motion is presently being appealed.

Defendants have filed motions to dismiss based on a wide variety of grounds. On March 29, 1966, I requested briefs from the parties on some of these grounds, including the ground of primary jurisdiction. For the reason set forth below, I find that this suit must be dismissed on all counts, as to all defendants.

I.

Plaintiffs seek an injunction against alleged present and future acts of defendants which interfere with the use of Krebiozen and investigation of it. In light of the fact that only prospective relief is sought, the complaint contains a fundamental and fatal defect. All of the alleged acts of defendants can be of no consequence and can cause plaintiffs no injury if Krebiozen is not available for distribution, use or investigation. The complaint does not sufficiently show that the sponsors of Krebiozen, who are not parties to this suit, are able or willing to provide Krebiozen for any purpose at some future date if plaintiffs succeed here. Without sufficient allegation of the availability of Krebiozen, this lawsuit is moot on the face of the complaint. This court does not have power to hear a moot case or issue an order which can have no effect on the rights or interests of the parties. If there is no Krebiozen, there is no order this court can enter which will give plaintiffs the ultimate relief they seek.

In view of the fact that the complaint states, on its face, a moot cause of action, the entire complaint as to all defendants is dismissed.

II.

The prayer for relief seeks an order enjoining defendants "from impeding, hindering or impairing the free uncommercial flow of Krebiozen interstate . . . to the physicians of the plaintiffs . . . for the purpose of continued human experimentation on the plaintiffs by their doctors . . . ." Krebiozen is a "new drug"; introduction of new drugs into interstate commerce is governed by 21 U.S.C. Section 355, subsection (a) of which provides, as follows:

> "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug."

Subsection (b) provides for a detailed application, including reports of tests made of the drug, a statement of the composition of the drug, a description of the methods and conditions of manufacture, and samples of the drug if requested. The application must be filed by a person who wishes to "introduce or deliver for introduction into interstate commerce" the drug in question.

A second procedure for gaining legal access to the channels of interstate commerce for a new drug is available under section 355(i), which provides:

> "The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs."

Exhaustive regulations have been promulgated; they appear at 21 C.F.R. section 103.3. Compliance with these regulations no doubt would require the expenditure of substantial time and effort by the sponsor of an investigational drug.

As the matter appears before me today, the provisions of section 355 offer an open door to the channels of interstate commerce for Krebiozen. The failure of the substance's sponsors to employ the statutory provisions is the present obstacle to unfettered interstate distribution. In 1963, a section 355(i) notice was filed; but it was withdrawn shortly after filing. In April, 1966, the substance's sponsors filed a "Notice of Claimed Investigational Exemption" for Krebiozen with the Food and Drug Administration ("FDA") Commissioner. As the sponsor must have known, the notice did not approach compliance with the clear requirements of the section 355(i) regulations. Looking over the history of the relationship between Krebiozen and the FDA for the last several years, I find a comparatively consistent refusal to use the avenue for interstate distribution of drugs which Congress has established.

Plaintiffs claim that Krebiozen's sponsors need not invoke the remedy provided by Congress. However, it is too well settled to require extended discussion that where Congress creates an expert administrative agency to perform a specific regulatory task which requires expertise, the agency cannot be bypassed. All matters properly within the agency's scope of authority must be referred to this agency for action in the first instance.

This rule applies to Krebiozen, even though the complaint in this case is framed in terms of the civil rights and anti-trust statutes. Clearly, until an invocation of

the provisions of section 355 has proved fruitless, there is no possible equitable relief that can be granted that does not directly interfere with the FDA's jurisdiction. Whatever injury plaintiffs presently suffer as a result of restrictions on interstate distribution of Krebiozen is the result of the operation of the Food, Drug and Cosmetic Act, and not of illegal activity by the defendants.

Even if the FDA were to act arbitrarily, unfairly or on the basis of a mistake of law, resort to a United States District Court is not permitted. The entire regular course of appeal from FDA action must first be employed. In this case, since direct appeal from a holding that a Section 355 (i) application is insufficient cannot be taken, Krebiozen's sponsors would have to file a section 355(b) application. If that were denied then the sponsors could appeal FDA action under both section 355(i) and section 355(b) in the appropriate Court of Appeals. Section 355(h); *Turkel* v. *Food and Drug Administration*, 334 F. 2d 833 (6th Cir.), *cert den.* 379 U.S. 990 (1964).

The entire regulatory scheme, including the appellate procedure is reasonable. Although compliance with it may impose substantial burdens on Krebiozen's sponsors, these burdens are reasonable in light of the public purpose to be served. Under the doctrine of primary jurisdiction. I cannot enter an order bypassing this regulatory scheme, particularly where compliance with it has not even been seriously attempted. Until the sponsors of Krebiozen choose to comply with the law, this court cannot entertain a suit which seeks to bypass that law.

This general rule of primary jurisdiction may give way if there is a non-frivolous challenge to the constitutionality of the statute establishing the regulatory scheme. Plain-

tiffs attempt to raise such an issue here. The argument is that Krebiozen is to be distributed free of charge solely for investigational purposes and that therefore it is not in commerce. If Krebiozen is indeed not in commerce, regulation of it would be beyond Congress' constitutional authority.

Plaintiffs' argument, even if they have standing to raise it, is plainly without merit. Congress may constitutionally regulate interstate shipments which do not involve purchase or trade. See e.g., *United States* v. *Underwriters Ass'n.*, 322 U.S. 533, 549-50 (1944); *Hoke* v. *United States*, 227 U.S. 308 (1913). The fact that Krebiozen is intended for investigational use by private doctors and their patients does not exempt it from the broad scope of congressional power, as long as it is transported across state lines.

Furthermore, there is no unconstitutional interference with the doctor-patient relationship. The freedom of a doctor to care for a patient according to his own judgment does not extend to an opening of the channels of interstate commerce to any substance the doctor seeks on the doctor's own terms. Congress has the power to impose reasonable regulations on the interstate traffic of drugs, even though such regulation necessarily has some impact on some doctor's practice of medicine.

Because I find no conflict with the Constitution in the application of 21 U.S.C. section 355 to Krebiozen, I find no basis for bypassing the reasonable regulatory scheme in this case. Until Krebiozen's sponsors comply with the law, this court cannot hear a case seeking unfettered interstate distribution of the substance regardless of what basis is alleged for this relief. For these reasons, so much of the amended complaint as seeks an injunction against interference with interstate distribution of Krebiozen would have to be dismissed as to all defendants, were the entire case not otherwise disposed of.

## III.

Relief is sought under the Civil Rights statutem 42 U.S.C. sections 1983-1985. A prequiaite to success under these sections is a fact finding that defendants are or will be acting under color of state law. Ordinarily at least one participant in the alleged misconduct must be a state institution, agency or employee. In the present case only UI and some of its employees among all of the named defendants, appear to be direct agents of the state.

Since this this is a suit for an injunction, the action to be enjoined must be taken under color of state law. The only action by UI or its employees alleged in the complaint which has any current relevance is the alleged official policy of the University prohibiting any person connected with UI from having anything at all to with Krebiozen. While this may raise some civil rights problems for some people within UI, it does not directly injure plaintiffs or deny them any federally protected right. This official UI policy presents no significant barrier to active and thorough use and investigation of Krebiozen. Consequently, the complaint fails to state a claim upon which relief can be granted against UI or its employees under the Civil Rights statute.

No other named defendant is alleged to be a state agent. The mere fact that AMA and ACS are corporations owing their existence to state law does not bring them within the scope of the "under color" requirement. Since the only defendants who could be directly liability under sections 1983-1985 are not liable in this case, the other defendants cannot be held under a conspiracy or joint action theory. Cf. *United States* v. *Price*, 383 U.S. 787 (1966).

For the above reasons, so much of the amended complaint as seeks relief under 42 U.S.C., sections 1983-1985 would be dismissed as to all defendants if this suit were not otherwise disposed of.

## IV.

The amended complaint is 243 pages long; it contains 1027 paragraphs (plaintiffs have numbered them; its prayer for relief runs six pages. It is redundant, large portions of it are immaterial; many paragraphs contain clearly scandalous matter. This amended complaint exhibits a rather thorough misconception of the function of a complaint and its proper functions. This amended complaint demonstrates that the drafter is either unable or unwilling to conform to the rather simple requirements of the Federal Rules of Civil Procedure, particularly Rules 8 and 9. This amended complaint fails in the elementary task which the Rules require it to perform: giving the parties and the court fair, clear and efficient notice of what it is plaintiffs are charging and what relief they seek.

For the purpose of more clearly indicating the magnitude of the problem presented by the amended complaint, I have listed below the paragraphs that would be stricken pursuant to Rule 12(f) from the first 75 pages, were the Herculean task of repair to be undertaken by this court. At the very minimum, the following paragraphs, and parts of paragraphs, would be stricken: 10 (last two sentences only), 11, 16, 17, 19, 20 (second sentence only), 21-24, 26, 32-34, 36-38, 43, 44, 52-58, 65, 69, 71-74, 76-78, 80, 90-95, 97-117, 123-125, 127-134, 136-142, 202, 203, 219, 220, 231-233, 255-257, 285-303, 306-309, 310-313 (however, exhibit 2 speaks for itself). This task was not pursued beyond page 75; the point has been made.

It is difficult for a court to fashion a proper response to such a grossly improper document. Courts ought to resist the temptation to simply dismiss a case and thereby delay or deny a proper hearing to plaintiffs simply because an attorney has ignored the basic precepts of pleading. None-

theless, an amended complaint such as this one offers no other recourse. It is wholly inadequate as it stands; selective striking to conform it to federal pleading standards would not only be an enormous task, but would also thoroughly dismember the document, perhaps leaving it inconsistent with plaintiffs' intent. Under these circumstances this court has no choice but to strike the entire complaint and dismiss the case. This is the course I would follow were this case not otherwise disposed of.

V.

Even assuming that any or all of the individual defendants are guilty of past illegal acts, the amended complaint does not sufficiently allege a threat of such acts in the future to permit an injunction to issue. Most of the individual defendants appear briefly in events which occurred three or more years ago; the amended complaint does not sufficiently allege that any of them can or will act in a similar way in the future. Under these circumstances, plaintiffs would not be entitled to an injunction. Consequently, this suit would be dismissed as to all individual defendants on all counts were it not otherwise disposed of.

VI.

Several questions of law remain unanswered in this case, including such questions as standing, venue and whether this is a proper Rule 23 class action. In light of the numerous other grounds for dismissing this suit outlined above, the court has not explored these additional questions.

For the reasons set forth in this letter of opinion, the complaint is dismissed as to all defendants of all counts. The order has been entered today.

Very truly yours,
Bernard M. Decker
United States District Judge

## APPENDIX C

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604
Tuesday, May 16, 1967

Before

Hon. JOHN S. HASTINGS, Chief Judge
Hon. ELMER J. SCHNACKENBERG, Circuit Judge
Hon. WIN G. KNOCH, Circuit Judge
Hon. LATHAM CASTLE, Circuit Judge
Hon. ROGER J. KILEY, Circuit Judge
Hon. LUTHER M. SWYGERT, Circuit Judge
Hon. THOMAS E. FAIRCHILD, Circuit Judge
Hon. WALTER J. CUMMINGS, JR., Circuit Judge

DR. F. ALLEN RUTHERFORD, ET AL.,
*Appellants-Petitioners,*

Nos. 15847, 15930 VS.

AMERICAN MEDICAL ASSOCIATION, ET AL.,
*Appellees-Respondents.*

### ORDER

This cause came on to be heard upon appellants-petitioners' Motion to Dispose of Pending "Petition for Rehearing and Reconsideration before Entire Court of Eight Judges," which motion asserts "Up until this date no action has been taken by the Court of Appeals on this Petition for Rehearing. . . ."

And the court being fully advised finds that the said motion is directed at the order of this court entered November 2, 1966 denying a petition for mandatory temporary injunction pending appeal; that on November 16,

1966 there was filed in this court a "Petition for Rehearing and Reconsideration before Entire Court of Eight Judges," and that each of the eight active members of this court separately voted to deny said petition for rehearing of the November 2, 1966 order on the following dates: Kiley, J. November 30, 1966; Cummings, J. Novemer 30, 1966; Swygert, J. December 1, 1966; Knoch, J. December 1, 1966; Castle, J. December 1, 1966; Schnackenberg, J. December 1, 1966; Hastings, C. J. December 1, 1966; and Fairchild, J. December 6, 1966; and that inadvertently the result of this unanimous vote was not communicated to the Clerk of the Court for entry on the record of this court.

It Is Therefore Ordered that the Clerk of this court be and he is hereby ordered to enter an order denying the petition for rehearing and reconsideration instanter, *nunc pro tunc* as of December 6, 1966, the date of the last vote cast as aforesaid.

And It Is Further Ordered that the motion to dispose of pending "Petition for Rehearing and Reconsideration before Entire Court of Eight Judges" is not entertained for the reason that the motion, in view of the foregoing findings, has become moot.

## APPENDIX D

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604
November 2, 1966

Before

Hon. ELMER J. SCHNACKENBERG, Circuit Judge
Hon. ROGER J. KILEY, Circuit Judge
Hon. LUTHER M. SWYGERT, Circuit Judge

DR. F. ALLEN RUTHERFORD, ET AL.,
*Petitioners-Appellants,*

No. 15847 vs.

AMERICAN MEDICAL ASSOCIATION, ET AL.,
*Respondents-Appellees.*

### ORDER

This cause came on to be heard upon the Verified Petition for a Mandatory Temporary Injunction Pending Appeal; on the Answers of the American Medical Association, the Board of Trustees of the University of Illinois, the American Cancer Society, and of several respondents represented by the United States Attorney; and on the replies to the answers; and upon supporting briefs and memoranda. And the court being fully advised,

It Is Ordered that the Verified Petition for a Mandatory Temporary Injunction Pending Appeal be, and it is hereby DENIED.

## APPENDIX E

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604
Wednesday, November 2, 1966

Before

Hon. ELMER J. SCHNACKENBERG, Circuit Judge
Hon. ROGER J. KILEY, Circuit Judge
Hon. LUTHER M. SWYGERT, Circuit Judge

EDWARD J. CRONLEY, SALLY RANISH, VERA MAE JEFFRIES, C. R. EASTER, DOROTHY WILLIAMS and CHESTER PLONSKI,
*Plaintiffs-Appellants,*
No. 15930 vs.
THE AMERICAN MEDICAL ASSOCIATION, ET AL.,
*Defendants-Appellees.*

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

On consideration of the petition in behalf of Edward J. Cronley, Vera Mae Jeffries, C. R. Easter, Dorothy Williams, and Chester Plonski, for permission to appeal as poor persons as provided by Section 1915, Title 28, U.S.C.A.,

It Is Hereby Ordered that leave be granted to the aforesaid petitioners-appellants to docket their appeal in this Court instanter *in forma pauperis* and that, as to said petitioners-appellants, the printing of their appendix and brief be waived provided that they file at least six (6) typewritten copies of their brief in lieu of printing same and serve at least one copy thereof on counsel for defendants-appellees.

It Is Further Ordered that this appeal be consolidated with appeal No. 15847—Dr. F. Allen Rutherford, et al. v. The American Medical Association, Inc., et al., for the purpose of hearing and disposition in this Court.

It Is Further Ordered that the motion of petitioner Edward J. Cronley to make the transcript of proceedings of September 30, 1966, in the District Court part of the record of proceedings now pending in petition to appeal *in forma pauperis* in this Court be, and the same is hereby denied.

## APPENDIX F

### CONSTITUTION OF UNITED STATES

### AMENDMENT IX—CONSTRUCTION OF ENUMERATED RIGHTS

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

### AMENDMENT X—RESERVED POWERS TO STATES

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

### AMENDMENT XIV

Section 1. All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Am., Art. 14, § 5

Section 5. The Congress shall have power to enforce, by appropriate legislation, the provisions of this article.

### TITLE 15, U.S.C.

26. Injunctive relief for private parties—Exception.—Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties,

against threatened loss or damage by a violation of the antitrust laws, including sections two, three, seven and eight of this act [§§ 13, 14, 18, and 19 of this title], when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity, under the rules governing such proceedings, and upon the execution of proper bond against damages for an injunction improvidently granted and a showing that the danger of irreparable loss or damage is immediate, a preliminary injunction may issue: Provided, That nothing herein contained shall be construed to entitle any person, firm, corporation, or association, except the United States, to bring suit in equity for injunctive relief against any common carrier subject to the provisions of the act to regulate commerce, approved February fourth, eighteen hundred eighty-seven [49 § 1 et seq.] in respect of any mater subject to the regulation, supervision, or other jurisdiction of the Interstate Commerce Commission. (Oct. 15, 1914, c. 323, § 16, 38 Stat. 737.)

## TITLE 28, U.S.C.

§ 1331. Federal question; amount in controversy

The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $3,000, exclusive of interest and costs, and arises under the Constitution, laws or treaties of the United States. June 25, 1948, c. 646, 62 Stat. 930.

§ 1343. Civil rights and elective franchise

The district courts shall have original jurisdiction of any civil action authorized by law to be commenced by any person:

(1) To recover damages for injury to his person or property, or because of the deprivation of any right or privilege of a citizen of the United States, by any act done in furtherance of any conspiracy mentioned in section 1985 of Title 42;

(2) To recover damages from any person who fails to prevent or to aid in preventing any wrongs mentioned in section 1985 of Title 42 which he had knowledge were about to occur and power to prevent;

(3) To redress the deprivation, under color of any State law, statute, ordinance, regulation, custom or usage, of any right, privilege or immunity secured by the Constitution of the United States or by any Act of Congress providing for equal rights of citizens or of all persons within the jurisdiction of the United States;

(4) To recover damages or to secure equitable or other relief under any Act of Congress providing for the protection of civil rights, including the right to vote. June 25, 1948, c. 646, 62 Stat. 932; Sept. 3, 1954, c. 1263, § 42, 68 Stat. 1241; Sept. 9, 1957, Pub.L. 85—315, Part III, § 121, 71 Stat. 637.

## TITLE 42, U.S.C.

§ 262. Regulation of biological products—Intrastate and interstate traffic; suspension or revocation of license as affecting prior sales

(a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District Court of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country or from any foreign country into any State or possession, any virus,

therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked licenes, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, or other product is plainly marked with the proper name of the article contained therein, the name, address, and licence number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

§ 284. Functions of Council

The Council is authorized—

Review of research problems

(a) To review research projects or programs submitted to or initiated by it relating to the study of the cause, prevention, or methods of diagnosis and treatment of Cancer, and certify approval to the Surgeon General, for prosecu-

tion under section 282 of this title, of any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of cancer;

Collection and dissemination of information

(b) To collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, and methods of diagnosis and treatment of cancer, by correspondence or by personal investigation of such studies, and with the approval of the Surgeon General make available such information through the appropriate publications for the benefit of health agencies and organizations (public or private), physicians, or any other scientists, and for the information of the general public;

Review of applications by research institutions for grants-in-aid

(c) To review applications from any university, hospital, laboratory, or other institution whether public or private, or from individuals, for grants-in-aid for research projects relating to cancer, and certify to the Surgeon General its approval of grants-in-aid in the cases of such projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of cancer;

§ 1983. Civil action for deprivation of rights

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities

secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress. R.S. § 1979.

§ 1984. Same; review of proceedings

All cases arising under the provisions of this Act in the courts of the United States shall be reviewable by the Supreme Court of the United States, without regard to the sum in controversy, under the same provisions and regulations as are provided by law for the review of other causes in said court. Mar. 1, 1875, c. 114, § 5, 18 Stat. 337.

§ 1985. Conspiracy to interfere with civil rights—Preventing officer from performing duties

(1) If two or more persons in any State or Territory conspire to prevent, by force, intimidation, or threat, any person from accepting or holding any office, trust, or place of confidence under the United States, or from discharging any duties thereof; or to induce by like means any officer of the United States to leave any State, district, or place, where his duties as an officer are required to be performed, or to injure him in his person or property on account of his lawful discharge of the duties of his office, or while engaged in the lawful discharge thereof, or to injure his property so as to molest, interrupt, hinder, or impede him in the discharge of his official duties;

(2) If two or more persons in any State or Territory Obstructing justice; intimidating party, witness, or juror conspire to deter, by force, intimidation, or threat, any party or witness in any court of the United States from attending such court, or from testifying to any matter pending therein, freely, fully, and truthfully, or to injure such party or witness in his person or property on account

of his having so attended or testified, or to influence the verdict, presentment, or indictment of any grand or petit juror in any such court, or to injure such juror in his person or property on account of any verdict, presentment, or indictment lawfully assented to by him, or of his being or having been such juror; or if two or more persons conspire for the purpose of impeding, hindering, obstructing, or defeating, in any manner, the due course of justice in any State or Territory, with intent to deny to any citizen the equal protection of the laws, or to injure him or his property for lawfully enforcing, or attempting to enforce, the right of any person, or class of persons, to the equal protection of the laws;

Depriving persons of rights or privileges

(3) If two or more persons in any State or Territory conspire or go in disguise on the highway or on the premises of another, for the purpose of depriving either directly or indirectly, any person or class of persons of the equal protection of the laws, or of equal privileges and immunities under the laws; or for the purpose of preventing or hindering the constituted authorities of any State or Territory from giving or securing to all persons with such State or Territory the equal protection of the laws; or if two or more persons conspire to prevent by force, intimidation, or threat, any citizen who is lawfully entitled to vote, from giving his support or advocacy in a legal manner, toward or in favor of the election of any lawfully qualified person as an elector for President or Vice President, or as a Member of Congress of the United States; or to injure any citizen in person or property on account of such support or advocacy; in any case of conspiracy set forth in this section, if one or more persons engaged therein do, or cause to be done, any act in furtherance of

the object of such conspiracy, whereby another is injured in his person or property, or deprived of having and exercising any right or privilege of a citizen of the United States, the party so injured or deprived may have an action for the recovery of damages, occasioned by such injury or deprivation, against any one or more of the conspirators. R.S. § 1980.

*Federal Food, Drug, and Cosmetic Act*

21 U. S. C. 355.

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either —

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the

basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or

not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: Provided, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis

of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or

has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary

shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such examption upon —

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the

investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(j) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is

or may be ground for invoking subsection (e) of this section: Provided, however, That regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

## NEW DRUG REGULATIONS
under the
FEDERAL FOOD, DRUG, AND COSMETIC ACT

§ 130.3 *New drugs for investigational use; exemptions from section* 505(a).

(g) A "Notice of claimed investigational exemption for a new drug" which pertains to a product subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), should be submitted initially to the Division of Biologics Standards, National Institutes of Health, Public Health Service, rather than to the Commissioner of Food and Drugs. Likewise, amendments of or supplements to such notice, and progress reports, consultations, or other communications with regard to the investigation, should be directed to the Division of Biologics Standards, which monitors the development of biological products subject to license under section 351 of the Public Health Service Act.

## FEDERAL RULES OF CIVIL PROCEDURE

**Rule 52.** ***Findings by the Court.***

(a) ***Effect.*** In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon and direct the entry of the appropriate judgment; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court. If an opinion or memorandum of decision is filed, it will be sufficient if the findings of fact and conclusions of law appear therein. Findings of fact and conclusions of law are unnecessary on decisions of motions under Rules 12 or 56 or any other motion except as provided in Rule 41(b). As amended Dec. 27, 1946, effective March 19, 1948.

Rule 65. *Injunctions*

(a) ***Preliminary; Notice.*** No preliminary injunction shall be issued without notice to the adverse party.

(b) ***Temporary Restraining Order; Notice; Hearing; Duration.*** No temporary restraining order shall be granted without notice to the adverse party unless it clearly appears from specific facts shown by affidavit or by the verified complaint that immediate and irreparable injury, loss, or damage will result to the applicant before notice can be

served and a hearing had thereon. Every temporary restraining order granted without notice shall be indorsed with the date and hour of issuance; shall be filed forthwith in the clerk's office and entered of record; shall define the injury and state why it is irreparable and why the order was granted without notice; and shall expire by its terms within such time after entry, not to exceed 10 days, as the court fixes, unless within the time so fixed the order, for good cause shown, is extended for a like period or unless the party against whom the order is directed consents that it may be extended for a longer period. The reasons for the extension shall be entered of record. In case a temporary restraining order is granted without notice, the motion for a preliminary injunction shall be set down for hearing at the earliest possible time and takes precedence of all matters except older matters of the same character; and when the motion comes on for hearing the party who obtained the temporary restraining order shall proceed with the application for a preliminary injunction and, if he does not do so, the court shall dissolve the temporary restraining order. On 2 days' notice to the party who obtained the temporary restraining order without notice or on such shorter notice to that party as the court may prescribe, the adverse party may appear and move its dissolution or modification and in that event the court shall proceed to hear and determine such motion as expeditiously as the ends of justice require.

## APPENDIX G

SUPREME COURT OF THE UNITED STATES

No. ....., October Term, 1967

F. ALLEN RUTHERFORD, ET AL.,

*Petitioners,*

vs.

AMERICAN MEDICAL ASSOCIATION, ET AL.

---

## ORDER EXTENDING TIME TO FILE PETITION FOR WRIT OF CERTIORARI.

---

Upon Consideration of the application of counsel for petitioner(s),

It Is Ordered that the time for filing a petition for writ of certiorari in the above-entitled cause be, and the same is hereby, extended to and including 19 November, 1967.

/s/ Abe Fortas
Associate Justice of the Supreme
Court of the United States

Dated this 13th day of
September, 1967.

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1967

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## No.

---

DR. F. ALLEN RUTHERFORD, et al.,
*Petitioners,*

vs.

THE AMERICAN MEDICAL ASSOCIATION, INC., et al.,
*Respondents.*

---

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit.

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## MEMORANDUM OF THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, GEORGE D. STODDARD, WARREN G. COLE AND DANELY SLAUGHTER IN OPPOSITION.

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Insofar as these respondents are concerned, plaintiffs' complaint, stripped of verbiage, alleges (Para. 264-407; App. 65-97) that, during the years 1951-1952 the University

of Illinois, George D. Stoddard, its then president, and Drs. Warren G. Cole and Danely Slaughter, members of its medical teaching staff, participated in an inquiry into the efficacy of Krebiozen as a remedy for cancer. Dr. Andrew C. Ivy, then vice president of the University, was the chief medical sponsor of Krebiozen. The inquiry resulted in a report which found, *inter alia,* that "the material known as Krebiozen . . . has not been identified chemically, is available only in bulky paraffin oil suspension rendering it unsuitable for many forms of laboratory experimentation . . . has no curative value in the treatment of cancer. . . . [I]t would be inconclusive if not futile to conduct further clinical investigation unless it is first possible to dispel the mystery which surrounds the nature of the material. In default of this no further consideration should be given to the problem." Ex. 6, amended complaint, App. 269.

Thereafter, the University adopted an internal policy that "there can be no further clinical uses or determinations of Krebiozen on the part of the staff members of the University of Illinois at any time . . . henceforth, Krebiozen is to be disassociated from service or research programs." App. 91.

Plaintiffs were not engaged in Krebiozen research at the University. Neither they nor their physicians have sought the administration or distribution of Krebiozen through the service or research programs of the University. Thus, the internal and essentially academic decision of the University that "there can be no further clinical uses or determinations of Krebiozen on the part of the . . . University" has not adversely affected plaintiffs. Accordingly, they do not have standing to complain of the decision. *Poe* v. *Ullman,* 367 U.S. 497, 504 (1960).

Nor does it appear from the complaint that the respondent, Board of Trustees, has denied plaintiffs a federally protected right so as to give rise to a cause of action under the Civil Rights Act. 42 U.S.C. §§1983-85. As the Court of Appeals correctly held, "there is no legal requirement that the University . . . permit its personnel to experiment with Krebiozen or to endorse it, and plaintiffs have no more right to Krebiozen experimentation at the University . . . than they do at any research institution." App. 6.

The remaining allegations of the amended complaint and the petition here and the opinion below relate to other respondents.

The petition for writ of certiorari should be denied.

Respectfully submitted,

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Urbana, Illinois

PRENTICE H. MARSHALL
227 Law Building
Champaign, Illinois

# In the Supreme Court of the United States

OCTOBER TERM, 1967

No. 843

DR. F. ALLEN RUTHERFORD, ET AL., PETITIONERS

*v.*

THE AMERICAN MEDICAL ASSOCIATION, INC., ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT*

**MEMORANDUM FOR THE RESPONDENT EMPLOYEES OF THE UNITED STATES IN OPPOSITION**

On January 3, 1966, petitioners[1] filed a complaint for injunctive relief in the United States District Court for the Northern District of Illinois under the provisions of the Sherman Antitrust Act (15 U.S.C. 26) and the civil rights statutes (42 U.S.C. 1983–1985).

As amended, the lengthy complaint alleged in essence that respondents[2] combined and conspired to

[1] Petitioners are a doctor and several cancer patients who brought this suit as a class action.

[2] Respondents include the American Medical Association, the American Cancer Society, the University of Illinois, and employees of the Federal Food and Drug Administration and the Public Health Service, as well as "other persons unknown." This memorandum is filed on behalf of the Federal employees named in the pleadings.



285-230—67

discredit the medical efficacy of the alleged anti-cancer drug, Krebiozen, and to impede the interstate distribution of that drug to those who wished access to it. Petitioners alleged that the American Cancer Society (allegedly a part owner of the anti-cancer drug, 5–FU) secured a monopoly in the distribution of anti-cancer drugs and that the impediment to the interstate distribution deprived petitioners of their civil rights. The district court, without considering the merits of the allegations regarding a conspiracy, found that the sponsors of Krebiozen had never made a bona fide attempt to have the drug licensed for interstate distribution under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355(a)–355(i), and that it was this failure on the part of the sponsors to comply with the licensing procedures, rather than the alleged misconduct of respondents, which prevented and would continue to prevent the interstate distribution of Krebiozen. It found that an injunction against respondents would in the circumstances be futile. Accordingly, for this and other reasons, it dismissed the complaint.[3] The court of appeals affirmed.

There is no occasion for further review. The gravamen of petitioners' complaint is that Krebiozen is denied access to the channels of interstate commerce,

[3] Other reasons given for dismissal by the district court were the failure to state a cause of action under the civil rights statutes, the failure sufficiently to allege that the conspiracy would continue in the future, and the failure of the complaint to measure up to the basic precepts of pleading. The court did not consider the other serious questions, such as standing, venue, the propriety of the Rule 23 class action, and the adequacy of the cause of action framed under the Sherman Act.

and that, as a result, they are denied its use. As the court below stated, however, petitioners' request should be directed to the sponsors of the drug, rather than to respondents (Pet. App. 4). Unless and until the sponsors seek and obtain approval for interstate distribution under the applicable provisions of Federal law, petitioners will be unable to obtain the drug in interstate commerce.

Referring to excerpts from correspondence between the sponsors of the drug and the Food and Drug Administration, petitioners allege that all attempts to gain approval would be rejected (Pet. 13–15, 19–20, 31–34), and from this premise they seek judicial permission to have the drug shipped in interstate commerce without compliance with the statute and the regulations. All that the correspondence shows, however, is that the Food and Drug Administration, in rejecting "new drug" applications as incomplete, also suggested that the sponsors submit future applications to the Laboratory of Biologics Control.[4] This scarcely shows that a proper application, supported by the necessary data, would not be given proper consideration.[5]

In these circumstances, it is respectfully submitted that the complaint was properly dismissed, and that

[4] The suggestion was made on the basis of the sponsors' own supporting data to the effect that Krebiozen was an extract from the blood of horses, and as such was subject to the jurisdiction of the Virus, Serum and Toxin provisions of the Public Health Service Act of 1944.

[5] There is no application pending at this time.

the petition for a writ of certiorari should therefore be denied.

ERWIN N. GRISWOLD,
*Solicitor General.*
FRED M. VINSON, JR.,
*Assistant Attorney General.*
BEATRICE ROSENBERG,
LAWRENCE P. COHEN,
*Attorneys.*

DECEMBER 1967.

U.S. GOVERNMENT PRINTING OFFICE: 1967

SUPREME COURT, U.S.
FILED
DEC 21 1967
JOHN F. DAVIS, CLERK

No. 843

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1967.

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DR. F. ALLEN RUTHERFORD, ET AL.,
*Petitioners,*

v.

THE AMERICAN MEDICAL ASSOCIATION, INC., ET AL.,
*Respondents.*

---

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

---

## BRIEF FOR RESPONDENTS AMERICAN MEDICAL ASSOCIATION, INC., OLIVER FIELD, DR. ALBERT SEGALOFF, AND DR. AUSTIN SMITH, IN OPPOSITION TO CERTIORARI.

---

DON H. REUBEN,
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THE GUNTHORP-WARREN PRINTING COMPANY, CHICAGO

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IN THE

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OCTOBER TERM, 1967.

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No. 843.

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THE AMERICAN MEDICAL ASSOCIATION, INC., ET AL.,
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ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

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## BRIEF FOR RESPONDENTS AMERICAN MEDICAL ASSOCIATION, INC., OLIVER FIELD, DR. ALBERT SEGALOFF, AND DR. AUSTIN SMITH, IN OPPOSITION TO CERTIORARI.

---

MAY IT PLEASE THE COURT:

We respectfully submit that the petition should be denied. The judgment below is plainly correct and in accord with all relevant precedents. There is no conflict between circuits (petitioners in fact claim none); nor does the

petition present any question of special or recurring importance.[1]

## I. THE DECISION BELOW IS CLEARLY CORRECT.

In essence, what the petitioners are seeking in this action is unlimited interstate distribution of an alleged "cure" for cancer—"Krebiozen"—without any compliance whatsoever with federal statutes and regulations pertaining to drugs and medicines. Petitioners are not the developers or sponsors of Krebiozen, but are instead persons who claim to be "deprived" of it because of its unavailability in commerce. During the entire 16-year controversy concerning this substance, the developers and sponsors have inexplicably refused to submit Krebiozen to the independent analysis and testing procedures of the Food and Drug Administration (FDA) established pursuant to the federal Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. §355).

The FDCA delegates to the FDA primary jurisdiction to determine the safety and the effectiveness of all new drugs; the Act establishes the only procedure by which a new drug may be released in commerce for public use, either in the regular course of trade or for experimental purposes.[2] Although petitioners allege a sinister

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1. In addition, the petition plainly does not conform to the requirements of clarity and conciseness under Rule 23(4) of this Court's Rules. The 53-page petition, with its 17 "Questions Presented," fits the same description applied by the Court of Appeals to the petitioner's complaint, *i.e.*, "general, irrelevant, vituperative, scandalous and conclusory." (Petition Appendix p. 2.)

2. § 355(a) of the Act provides:

> "(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) of this section is effective with respect to such drug."

Subsection (b) requires the filing of a detailed application reporting preliminary tests, composition of the substance,

*(Continued on Next Page)*

and diabolic "conspiracy" among respondents to interfere with the testing and approval of Krebiozen, they do not and cannot claim that any bona fide attempt has ever been made by Krebiozen's sponsors to comply with the regulatory procedures prescribed by Congress and the FDA. As the Court of Appeals succinctly observed:

> "Until someone has attempted to comply with the Act with respect to Krebiozen, plaintiffs' appeal should be to the sponsors of the drug." (Petition Appendix, p. 4.)

## II. PETITIONERS' ARGUMENTS ARE WITHOUT MERIT.

Petitioners' contentions that the FDCA does not apply to Krebiozen are insupportable and fly in the face of the plain meaning and history of the statute. Federal regulation under the Commerce Clause is not limited to goods or articles distributed without a monetary exchange. *United States* v. *South Eastern Underwriters Ass'n*, 322 U. S. 533, 549-50 (1944); *Hipolite Egg Company* v. *United States*, 220 U. S. 45 (1911). Toxicity is not the sole criterion prescribed by the FDCA for testing new drugs; effectiveness "for use under the conditions prescribed, recommended or suggested," as well as safety, is an equally applicable consideration. *United States* v. *Allan Drug Corp.*, 357 F. 2d 713, 718 (10th Cir. 1966).

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the method and condition of manufacture and a sample of the drug itself, if requested.

If a drug is to be distributed for experimental purposes only, the sponsor may apply for an exemption from the new drug application requirements of §§ 355(a) and (b) under subsection (i) which provides:

> "(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. . . ."

Equally without merit is petitioners' argument that Krebiozen is not subject to federal regulation because it is not a "drug" within the scope of the FDCA and that the mixture cannot be regulated under the Public Health Act (42 U. S. C. A. § 262). As the Court of Appeals held, there is no "gap" or "no-man's land" between the FDCA and the Public Health Act so that a substance such as Krebiozen could be freely distributed as a "cure" for cancer year after year, without any federal testing or supervision. If Krebiozen or any other alleged medicine could be dispensed to the public and represented as a cure for disease without the approval of the FDA, the entire regulatory scheme designed to protect the public safety would be seriously jeopardized, if not destroyed. This is exactly what petitioners seek under the guise of a suit for a permanent injunction.

## CONCLUSION.

For the foregoing reasons we submit the petition for certiorari should be denied.

Respectfully submitted,

DON H. REUBEN,
KARL F. NYGREN,
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ELSIE C. SPEARS,
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*Attorneys for Respondents.*

December 20, 1967.

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No. 843

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JOHN F. DAVIS, CLERK

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1967

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DR. F. ALLEN RUTHERFORD, Louise Walther, Sally Ranich, Vera Mae Jeffries, C. R. Easter, Dorothy Williams, each in behalf of their own person, and in behalf of all persons afflicted with cancer, and approximately thirty-two million Americans now living who will die with cancer,

*Petitioners,*

v.

THE AMERICAN MEDICAL ASSOCIATION, INC., an Illinois Corporation, The American Cancer Society, Inc., a New York Corporation, The American Cancer Society, San Francisco Division, California, and Dr. _____ Batchelder (first name unknown) and

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, Dr. Warren G. Cole, Dr. Danley Slaughter, Dr. Virginia Pierce, Dr. George D. Stoddard, and

DR. KENNETH M. ENDICOTT, Arthur Furst, Paul Kirk, Gene R. Hay, Michael Deddish, Joseph M. Regan, Guy F. Robbins, Albert Segaloff, Austin Smith, Henry A. Szujewski, Paul Wermer, Oliver Field, R. Edwin Moore, Daniel Abrahamson, John William Blue, Mrs. John W. Blue, Carl R. Baurlen, William E. Braunig, R. W. Case, Joseph Cox, Gilbert Goldhammer, John R. Heller, William Kupp, Boisfeullet Jones, George P. Larrick, T. C. Maariveglia, Howard Mayfield, Willard G. Orr, Robert Palmer, Thomas Rice, George Schwartzman, Clifford Shane, R. D. Sherman, Ted J. Smolenski, Norman P. Booker, and other persons unknown,

*Respondents.*

---

## PETITION FOR REHEARING OF PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

---

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IN THE

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DR. F. ALLEN RUTHERFORD, Louise Walther, Sally Ranich, Vera Mae Jeffries, C. R. Easter, Dorothy Williams, each in behalf of their own person, and in behalf of all persons afflicted with cancer, and approximately thirty-two million Americans now living who will die with cancer,

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THE AMERICAN MEDICAL ASSOCIATION, INC., an Illinois Corporation, The American Cancer Society, Inc., a New York Corporation, The American Cancer Society, San Francisco Division, California, and Dr. ———————— Batchelder (first name unknown) and

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, Dr. Warren G. Cole, Dr. Danley Slaughter, Dr. Virginia Pierce, Dr. George D. Stoddard, and

DR. KENNETH M. ENDICOTT, Arthur Furst, Paul Kirk, Gene R. Hay, Michael Deddish, Joseph M. Regan, Guy F. Robbins, Albert Segaloff, Austin Smith, Henry A. Szujewski, Paul Wermer, Oliver Field, R. Edwin Moore, Daniel Abrahamson, John William Blue, Mrs. John W. Blue, Carl R. Baurlen, William E. Braunig, R. W. Case, Joseph Cox, Gilbert Goldhammer, John R. Heller, William Kupp, Boisfeullet Jones, George P. Larrick, T. C. Maariveglia, Howard Mayfield, Willard G. Orr, Robert Palmer, Thomas Rice, George Schwartzman, Clifford Shane, R. D. Sherman, Ted J. Smolenski, Norman P. Booker, and other persons unknown,

*Respondents.*

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## PETITION FOR REHEARING OF DENIAL OF PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Petitioners pray that this Court grant a rehearing of its order of January 15th, 1968, denying the petition for a writ of certiorari in the above entitled case and that a writ of certiorari issue to review the judgment of the Court of Appeals for the Seventh Circuit in the above entitled case as prayed for in the petition filed November 20, 1967, which judgment dismissed the suit of petitioners seeking to establish their right to enjoin a conspiracy denying them as individuals the fundamental Constitutional right to life and survival through access to and use of a non-toxic medical remedy of their own choice, which has alleviated their affliction and is necessary for their survival, where no other effective remedy exists for them and they have hitherto been declared terminal.

## REASONS FOR GRANTING REHEARING AND ISSUING WRIT

1. The threatened mortal jeopardy which these petitioners prayed this Court to avert has now materialized.

The petitioners have now been advised by the sponsors that, by reason of threat of criminal prosecution by Government Agencies, they are unable to distribute to the petitioners, or any other cancer patients similarly situated, the anti-cancer remedy Krebiozen which has alleviated their affliction and is vital to their continued survival and freedom from pain. As a consequence they, and other cancer patients similarly situated and otherwise pronounced doomed, if this court, their last resort, continues to refuse to entertain their plea, will now painfully die.

They will so die regardless of, and long before completion of, any possible compliance by the sponsors with any relevant or applicable federal statutory and administrative regulatory procedures for permissive interstate distribution of, to them, this vital remedy. This is especially so where, as in this case, such procedure involves public rectification of past erroneous and gratuitous, prejudging,

published reports by regulatory federal agencies knowingly falsely denying [1] even the physical existence of this remedy [2] and, a fortiori, its effectiveness.

2. This petition therefor presents to this Court, the question whether it will reconsider its refusal to exercise its discretion to permit the saving of the lives of these petitioners and of thousands of other pronounced "hopeless" cancer victims.

The sworn testimony and documented voluminous scientific, chemical and clinical reports and exhibits submitted and filed with this Court, subject to its examination, demonstrate that Krebiozen is prima facie effective to arrest and alleviate the otherwise fatal cancer of these victims. No evidence to the contrary has been submitted. These petitioners advise that they are prepared to substantiate the effectiveness of this remedy in a hearing by testimony of recognized independent scientific laboratories and of more than nine hundred reputable physicians who have themselves actually treated "terminal" cancer patients with this remedy.

The respondents are accused of preventing the petitioners and such other cancer victims from obtaining this life preserving remedy (even though, and whether or not, the sponsors [3] have repeatedly tried, as they have in 1954

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[1] See Congressional Record of December 6, 1963, pages 22492-22504 (pages 10-22 of reprint copy attached to original of petition) containing verbatim submitted and known reports scientifically differentiating Krebiozen from creatine as to infra-red spectrographic and as to chemical analysis, made by the Anderson Physical Laboratory, Urbana-Champaign, Illinois, and by the Clark Microanalytical Laboratory, Urbana, Illinois—also a report that the N. C. I.'s own combustion analysis showed a carbon content for Krebiozen of only 21 per cent as contrasted with a carbon content for creatine of 36.6 percent.

[2] Nevertheless the F. D. A. autocratically adheres to its published pronouncement of September 7, 1963, that it has determined Krebiozen to be no more than creatine, a harmless but ineffective body substance, which finding it reiterates is "scientifically unimpeachable".

[3] The sponsors have in no way contributed, directly or indirectly, to this suit, financially or otherwise.

and 1961 under the F.D.C.A. Act, or may try again,[4] to obtain federal license to distribute it). As the Court of Appeals expressly recognizes, this accusation inescapably constitutes "a full frontal attack on defendants, the American Medical Association, The American Cancer Society . . .". However, it does not, and cannot, constitute an attack on "the medical profession generally", as that Court would hold, since the members thereof, as members of, dependent for medical information on, and subject to professional and economic disciplining by that Association, have today no direct or effective elective or representative voice in its management or actions. Nor can it constitute an attack, as that Court would also hold, against "the Federal Food and Drug Administration", which is not even joined as a respondent.

At no point have these respondents substantiated any denial of these allegations constituting this accusation.

The Court of Appeals and the District Court refuse to countenance such a "frontal attack" where made against respondents such as the American Medical Association and the American Cancer Society. Such Courts have instead resolutely refused to grant a hearing which would permit the disclosure of the true facts as to this unnecessary past and continuing sacrifice of life, and put a stop to it.[5] Will

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[4] The futility, however, of any such new application is apparent from the article derogating Krebiozen, published in 1966 by the American Cancer Society for continuing circulation among members of the American Medical Association staffing federal agencies and practicing outside of such agencies. This article has just come to petitioners' attention and a facsimile is attached to the original of this petition. Attention is also directed to the article of April 17, 1967, (while this suit has been in progress) published in the Journal of the American Medical Association for similar circulation (collaborated in by respondent, Gilbert Goldhammer) entitled "The Krebiozen Story—Is Cancer Quackery Dead?" which quotes the public statement of the Commissioner of the F.D.A. that Krebiozen is "a cruel hoax. Each day a person with treatable cancer relies upon Krebiozen is a day that brings him closer to death." A facsimile of this article is also attached to the original of this petition.

[5] Attention is directed to the record in this case.

not this Court do otherwise, to permit the saving of the lives of these Petitioners and other cancer victims similarly situated?

3. These lower Courts have now established that the right of a private individual to unfettered access to a non-toxic vital medical remedy of such individual's own free choice is judicially unenforceable and therefore illusory. This Court in the past has been alert to validate individual liberty and the concept that government is the servant of the people, not their master. This Court, it is submitted, should not now permit the judicial validation by these lower Courts of this bureaucratic and monopolistic usurpation of dominion over all citizens in medical matters, especially when such dominion is used, as now, to fatally jeopardize the lives of the petitioners and all other cancer victims similarly situated.

4. There are attached copies of letters of the sponsors of Krebiozen, received since this Court denied the Petition for Certiorari, advising that by reason of the threat of prosecution of such sponsors made through agents of the Food and Drug Administration, although they are willing and desirous, they are unable to distribute Krebiozen, even without charge, to the petitioners. The original letters are attached to the original of this petition.

5. There are also attached affidavits of reputable physicians of the petitioners and others averring that continued administration to them of Krebiozen is vital to their continued survival and freedom from pain. The original affidavits are also attached to the original of this petition.

## *Conclusion*

For the reasons set forth above and in the petition for writ of certiorari, it is respectfully urged that considerations of humanity, society and Constitutional rights warrant that a rehearing be granted and that upon such rehear-

ing a writ of certiorari issue to the Court of Appeals for the Seventh Circuit, or in the alternative, that the decision of that Court be vacated and this suit remanded to the District Court for a hearing on the facts.

Respectfully submitted,

FRANK O. WALTHER
*Attorney for Petitioners*

## CERTIFICATE OF COUNSEL

I hereby certify that the foregoing petition for rehearing is presented in good faith and not for delay, but because of the exigencies of the present situation, involving preservation of life, and is restricted to grounds specified in Rule 58 of the Rules of this Court.

FRANK O. WALTHER
*Attorney for Petitioners*

# EXHIBITS

Letter of Dr. Ivy dated January 31, 1968

Letter of Judge Durovic dated January 26, 1968

Affidavits of doctors as to effectiveness and necessity of continued availability of Krebiozen for their patients

ROOSEVELT UNIVERSITY

430 SOUTH MICHIGAN AVENUE

CHICAGO 5, ILLINOIS • WABASH 2-3580

January 31, 1968

Messrs. Louise Walther,
Sally Ranich, Vera Mae Jeffries
and C. R. Easter

Dear Sir and Mesdames:

To write this letter gives me great anxiety and heartsickness as I fully realize its effects on all of your lives by the denial of the anticancer therapy which, in my opinion and in the opinion of hundreds of eminent physicians has prolonged those lives. My long experience in medicine teaches me that Krebiozen or its equivalent Carcalon show great promise of making valuable contributions to human knowledge in the control and management of the disease of cancer with which all of you are afflicted. Each and every one of you were told by members of the medical profession that your lives were near at an end years ago. As a scientist in the field of medicine I am fully convinced that Krebiozen or its equivalent Carcalon have prolonged them and its further administration would prolong them indefinitely. However, this cannot be done as I can no longer furnish this therapy to you through your doctors for scientific and experimental research outside of the State of Illinois despite the fact that the Department of Health, Education, and Welfare has in both the years 1954 and 1961 determined that Krebiozen comes within the provisions of the Public Health Service Act and not under the Federal Food, Drug and Cosmetic Act, and that under the provisions of the Public Health Service Act, the Attorney General of the United States had ruled in 1912 that substances which come within the provisions of the Public Health Service Act can be legally distributed interstate for scientific and experi-

mental research, so long as they are not for sale, barter, or exchange. I have never taken a penny for either Krebiozen or Carcalon in my life nor do I intend to do so. My interest is exclusively scientific.

However, I must inform you that the agents of the Food and Drug Administration have called on me, and that agency has written to me a letter to the effect that (1) they have evidence that I have been giving out Krebiozen or its equivalent Carcalon to people to carry over state lines, and (2) that they consider such action to be illegal under the Federal Food, Drug and Cosmetic Act. Mr. John Sembower, my attorney and I have believed such action to be legal, since the product is not for sale, barter, or exchange under the supervision of a licensed physician. That is why I have been giving it to you and other patients.

I went to Washington to see an attorney who is a specialist in the Food and Drug Administration Law, and he advises me to cease giving it to persons to take the therapy out of the state. So, you can see why, regardless of my humane feelings and great desire, and regardless of my conviction that Krebiozen or its equivalent, Carcalon does prolong your lives, and that irreparable damage to your lives will result in its denial, that although I wish to give this remedy free of charge to you and other patients to be used by your physicians for scientific and experimental research, exclusively, I must, unfortunately defer to this attorney's advice.

With best wishes, I am

Very sincerely yours,

A. C. IVY, M.D.

**KREBIOZEN RESEARCH FOUNDATION**

*a nonprofit organization devoted to research*

Suite 2324, Bankers Building

105 WEST ADAMS STREET, CHICAGO, ILLINOIS 60603

DEarborn 2-3515

January 26, 1968

Messieurs and Mesdames Louise Walther,
Sally Ranich, Vera Mae Jeffries, C. R. Easter
and Dorothy Williams
c/o Frank O. Walther, Esquire
130 Booth Lane
Haverford, Pennsylvania

Although we are able and willing to furnish you with Krebiozen, without charge, it is with regret that I must inform you that it is no longer possible for the above Foundation to furnish it to you or any other cancer patient living outside the state of Illinois until the question as to whether it is legally permissible to ship Krebiozen to such patients has been legally resolved.

Steven Durovic, M. D.,

by
/s/ Marko Durovic

Marko Durovic
acting under Power-of-Attorney

# AFFIDAVITS

County of Denver :
State of Colorado : SS.

I, LOUIS L. RETALLACK, M.D., being duly sworn according to law depose and say:

1. I am a duly licensed physician under the laws of the state of Colorado and practice my profession in the county of Denver, state of Colorado.

2. Presently I am treating a patient afflicted with the disease of cancer with the drug known as Krebiozen. The results of this treatment are in my opinion beneficial in the control of the disease and it shows promise in making valuable contributions to human knowledge in the treatment of cancer.

3. My administration of Krebiozen for this patient has resulted in the substantial fulfilment of the following recognized medical criteria:

(a) The maintenance of the will to live through awareness that effective action is thus provided to alleviate the patient's symptoms and to arrest the disease.

(b) The reduction or eradication of the primary lesion and of other metastatic lesions.

(c) The reduction of pain and dispensation of necessity for pain relieving drugs.

(d) The lack of any harmful side effects in connection with the use of this drug.

4. Krebiozen in the case of this patient is fulfilling significantly the realization in this patient of the above four medical criteria and objectives which, in this case cannot thus be realized through the use of other recognized drugs, surgery or radiation therapy. I have no hesitation in stating that in my judgment, as an experienced physician,

Krebiozen has prolonged the life of this patient and ameliorated his condition and denial of further Krebiozen therapy to him would be inhumane and result in irreparable damage to his life and health.

5. The name and medical records of this patient now under my care will be made available to any court of competent jurisdiction upon order or request of such court.

LOUIS L. RETALLACK, M.D.

Sworn to before me on the 4th day of February, 1968.

GLADYS G. ROWLAND
Notary Public

My Commission expires Dec. 20, 1969.

County of Bucks :
State of Pennsylvania : SS.

I, HARVEY FEIGLEY, being duly sworn according to law depose and say:

1. I am a duly licensed physician under the laws of the state of Pennsylvania and practice my profession in the city of Quakertown, state of Pennsylvania.

2. Presently I am treating with the medical remedy known as Krebiozen a patient who was hopelessly terminal because afflicted with the disease of cancer. When initially administered the condition of the patient was such that he could not be conscious of the nature of the treatment administered. The results of this treatment are in my opinion beneficial in the control of the disease and for some years

it has now restored this patient to normal life pursuits. It shows great promise in making valuable contributions to human knowledge in the treatment of cancer.

3. My administration of Krebiozen for this patient has resulted in the fulfilment of the maintenance of the will to live through awareness that effective action is thus provided to alleviate the patient's symptoms and to arrest the disease, the reduction or eradication of the primary lesion and of other metastatic lesions, and the reduction of pain and dispensation of necessity for pain relieving drugs. There has been a lack of any harmful side effects in connection with the use of this remedy.

4. Krebiozen in the case of this patient is fulfilling significantly the realization in this patient of the above medical criteria and objectives which, in his case cannot thus be realized through the use of other recognized drugs, surgery or radiation therapy. I have no hesitation in stating that, in my judgment, as an experienced physician, Krebiozen has prolonged the life of this patient and ameliorated his condition and denial of further Krebiozen therapy to him would be inhumane and result in irreparable damage to his life and health.

5. The name and medical record of this patient now under my care will be made available to any court of competent jurisdiction upon order or request of such court.

HARVEY FEIGLEY, M.D.

Sworn to before me on the 3rd day of February, 1968.

ARTHUR G. BARTHOLOMEW
Justice of the Peace

My Commission expires Jan., 1972.

County of Lebanon :
State of Pennsylvania : SS.

I, M. DALE YOCUM, being duly sworn according to law depose and say:

1. I am a duly licensed physician under the laws of the state of Pennsylvania and practice my profession in the city of Lebanon, state of Pennsylvania.

2. Presently I am treating Dorothy Williams as a patient afflicted with the disease of cancer with the drug known as Krebiozen. The results of this treatment are in my opinion beneficial in the control of the disease and it shows promise in making valuable contributions to human knowledge in the treatment of cancer.

3. My administration of Krebiozen for this patient has resulted in the substantial fulfilment of the following recognized medical criteria:

(a) The maintenance of the will to live through awareness that effective action is thus provided to alleviate the patient's symptoms and to arrest the disease.

(b) The reduction or eradication of the primary lesion and of other metastatic lesions.

(c) The reduction of pain and dispensation of necessity for pain relieving drugs.

(d) The lack of any harmful side effects in connection with the use of this drug.

4. Krebiozen in the case of this patient is fulfilling significantly the realization in this patient of the above four medical criteria and objectives which, in her case cannot thus be realized through the use of other recognized drugs, surgery or radiation therapy. I have no hesitation in stating that, in my judgment, as an experienced physician, Krebiozen has prolonged the life of this patient and amelio-

rated her condition and denial of further Krebiozen therapy to her would be inhumane and result in irreparable damage to her life and health.

M. DALE YOCUM, M.D.

Sworn to before me on the 5th day of February, 1968.

ELIZABETH R. JAMES
Notary Public

My Commission expires Feb. 2, 1969.

County of Montgomery :
State of Pennsylvania : SS.

I, JAMES WOODROW CLARK, being duly sworn according to law depose and say:

1. I am a duly licensed physician under the laws of the State of Pennsylvania and practice my profession in the town of Wynnewood in the State of Pennsylvania.

2. I have treated several patients afflicted with the disease of cancer with the medical remedy known as Krebiozen. This remedy has been available to these patients without charge on all occasions. The results of this treatment in my opinion have been beneficial in the control of the disease and this substance shows promise in making valuable contributions to human knowledge in the treatment of cancer.

3. My administration of Krebiozen has been based upon the fulfilment of the following recognized medical criteria:

(a) Maintenance of the will to live.

(b) The maintaining of continuing awareness on the part of the patient that maximum action is being constantly taken to alleviate each symptom which develops, and to bring about an arrest of the disease.

(c) The employment of those therapeutic procedures which in the judgment of the responsible physician are best calculated to accomplish one or the other of all the following objectives:

(i) Eradication of the disease—to include the eradication of the primary lesion, and any metastatic lesions.

(ii) The amelioration of pain and other adverse signs and symptoms—whether eradication of the disease is considered to be highly probable, or is considered to be impossible.

(iii) The maintaining of the patient in the maximum state of physical, mental, and emotional well-being obtainable under the circumstances of the diseased state, and the therapeutic procedures.

(d) The side effects, which experience has demonstrated to be associated with a therapeutic procedure, should be inconsequential, or the impact of any significant side effects upon the physical and emotional state of the patient should be justified when compared with the *ultimate* benefit which may be expected from the therapeutic procedure.

4. Because Krebiozen in combination with other medical or surgical procedures, fulfills to a significant degree, especially in comparison with other cancer therapy, the requirements inherent in these four criteria, continuation of Krebiozen therapy is essential to the adequate medical

management of the several cancer patients who are now under my medical supervision. I have no hesitation in stating that, in my judgment as an experienced physician, Krebiozen prolonged the lives of these patients and denial of further Krebiozen therapy to these patients would be a great tragedy the result of which would be irreparable damage to the lives and well-being of these patients.

The names and medical records of these patients will be made available to any court of competent jurisdiction or on any order or request from such court.

JAMES WOODROW CLARK, M.D.

Sworn to before me the sixth day of February, 1968.

WILLIAM E. COMPTON
Notary Public

My Commission expires July 29, 1970.

SUPREME COURT. U. S.

Office-Supreme Court, U.S.
FILED
JAN 6 1968
JOHN F. DAVIS, CLERK

No. 843

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1967

DR. F. ALLEN RUTHERFORD, ET AL.,

*Petitioners,*

vs.

THE AMERICAN MEDICAL ASSOCIATION, INC., ET AL.,

*Respondents.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit.

## REPLY FOR THE PETITIONERS TO THE MEMORANDUMS OF THE AMERICAN MEDICAL ASSOCIATION, OLIVER FIELD, DR. ALBERT SEGALOFF, DR. AUSTIN SMITH, THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, DR. WARREN G. COLE, DR. GEORGE STODDARD, THE ATTORNEY GENERAL AND SOLICITOR GENERAL OF THE UNITED STATES AND OTHERS.

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## REPLY FOR PETITIONERS TO THE MEMORANDUMS OF THE AMERICAN MEDICAL ASSOCIATION, OLIVER FIELD, DR. ALBERT SEGALOFF, DR. AUSTIN SMITH, THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, DR. WARREN G. COLE, DR. GEORGE STODDARD, THE ATTORNEY GENERAL AND SOLICITOR GENERAL OF THE UNITED STATES.

On January 3, 1966, petitioners filed a complaint for injunctive relief in the United States District Court for the Northern District of Illinois under the provisions of

the Sherman Antitrust Act (15 U.S.C. 26) and the Civil Rights Statutes (42 U.S.C. 1983-1985). The suit is private in nature and no agency of the United States Government was made a party to the suit.

**ANSWERING RESPONDENTS, THE AMERICAN MEDICAL ASSOCIATION, FIELD, SEGALOFF, and SMITH, THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, COLE and STODDARD.**

In so far as these respondents are concerned, this Court must disregard completely the red herring defense of relying on any provisions of the Federal Food, Drug, and Cosmetic Act, or the enforcement thereof. No such defense is available to allegations of violations of the Sherman Act or the Civil Rights Act. This was made clear in *United States* v. *American Medical Association,* 110 F. 2d 703, cert. den. 310 U.S. 644. There, justification was sought for the commission of the crime that its commission benefited the community. "Neither the fact that the conspiracy is intended to promote the public welfare, or accomplish some ultimate good", or "even if it was for the purpose of enforcing the law . . . is sufficient to avoid the penalties of the Sherman Act." The instant case must receive the same treatment as this same respondent received in that case. *United States* v. *American Medical Association, supra.* We respectfully refer this Court to our citations from that case on pp. 27-29, in Petition for Certiorari. This Court must also consider the fact that this is an admitted continuous conspiracy which commenced in 1950, and still continues. From 1950 until June 1963 this red herring defense was not available to these respondents, and during this period we had the fraudulent and forged report of the American Medical Association

published in its Journal on September 27, 1951, and the fraudulent article by Szujewski in the same journal on March 27, 1952. All acts of each and every one of these respondents in this phase of the conspiracy are outlined with particularity from pages 39 to 66 in the Amended Complaint — perhaps with a little too much particularity — but Rule 9(b) of the Federal Rules of Civil Procedure does require this "particularity" and so do the decisions of this Court and the Court of Appeals. Webster, Winston, Brittanica, and Oxford dictionaries unanimously define the word "particularity" as "strict attention to detail; minute exactness; fastidiousness; peculiarity, and characteristic quality." *Sterns* v. *Page,* 48 U.S. 319; *Swift and Company* v. *United States,* 196 U.S. 375; *Chamberlain Machine Works* v. *United States,* 270 U.S. 349; *Ware-Kramer Tobacco Company* v. *American Tobacco Company,* 178 Fed. 117.

There can be little doubt but the participation of the respondents Cole, Pierce, and Slaughter, who acted under "color" of law from the State University of Illinois in this phase of the illegal scheme alleged, brings the conspiracy within the prohibitions of the Fourteenth Amendment and sections 1983-1985, Title 42, U.S.C. The decisions of this Court are unanimous on this question. *United States* v. *Price,* 383 U.S. 787; *United States* v. *Mosely,* 238 U.S. 383; *United States* v. *Guest,* 383 U.S. 745. Moreover, the American Medical Association *per se,* even in the absence of participation of Cole, Pierce, and Slaughter from the University of Illinois, is subject to the prohibitions of the Fourteenth Amendment. *Munn* v. *Illinois,* 94 U.S. 113; *Holden* v. *Hardy,* 169 U.S. 366; *Marsh* v. *Alabama,* 326 U.S. 51; *Evans* v. *Newton,* 382 U.S. 296; *Terry* v. *Adams,* 345 U.S. 461; *Hawkins* v. *North Carolina Dental Society,* 355 F. 2d 718.

As to the respondents, the Board of Trustees of the University of Illinois, Cole and Stoddard, the facts which constitute the fraud and conspiracy involved in the "Conclusions" and "Recommendations" by Cole and Stoddard are also stated with particularity from page 66 to page 97 in the Amended Complaint. These fraudulent "Conclusions" and "Recommendations" were released to the world on September 20, 1952. (P. 79, Amended Complaint). The question here involved is whether these "Conclusions" and "Recommendations" were fraudulent as alleged, and was their release in the furtherance of the conspiracy in violation of the Antitrust statutes. This is a matter of fact which can be resolved only on a hearing, and on competent legal evidence. It has nothing to do with any amendment of section 355(i), Title 21, U.S.C. effective eleven years later, nor were the acts of the respondent immunized retroactively by this amendment. Again we refer to the citation of the *United States* v. *American Medical Association,* 110 F. 2d 703, on the bottom of page 28, in the Petition for Certiorari: These petitioners have as much right "to sue for and have injunctive relief . . . against threatened loss or damage by a violation of the Antitrust Laws" under section 26, Title 15, U.S.C.A. as the Attorney General had to prosecute the American Medical Association in that case under similar statutes of Title 15, as long as the threatened loss or damage is the proximate result of the violations. *Mandeville Island Farms, Inc.* v. *American Crystal Sugar Company,* 334 U.S. 219, 236. Perhaps on a hearing in the District Court these respondents can show these charges unwarranted, or the petitioners cannot prove them, but for present purposes the charges must be taken as though their verity were established. In that light it is clear that the offenses alleged come within the condemnation of the Antitrust

and Civil Rights Statutes, *United States* v. *American Medical Association,* 110 F. 2d 703. The allegations of fact in the Amended Complaint are true or they are false, or they are partly true or partly false. To ascertain their verity requires a hearing in the District Court. To accomplish this, the most reasonable and expeditious procedure is to grant the Petition for Certiorari; vacate the judgment of the Court of Appeals; and remand the cause to the District Court for a hearing on these facts. If the Court sees fit it can suggest or order the Complaint amended. We have no brief from the respondent, The American Cancer Society, and have no comment thereon, having nothing to answer. For present purposes the report of the American Cancer Society in 1959 must be taken as a fraud as alleged in the Complaint. This brings us to the brief of the Solicitor General in behalf of some persons who were employed by the government, and some who were not.

## REPLY TO SOLICITOR GENERAL and ATTORNEY GENERAL

This memorandum correctly recognizes that petitioners allege that the "respondents combined and conspired to discredit the medical efficacy of the alleged anticancer drug, Krebiozen, and to impede the interstate distribution of that drug to those who wished access to it." This is the very gist of this lawsuit, and the questions are why does the American Medical Association combine and conspire to impede such interstate distribution, and what are the methods employed? The first question is answered by the fact that this Association is a trade monopoly and to ascertain this fact these gentlemen need only refer to their own indictment procured against this Association in Washington, D. C. a few years ago in *United States* v.

*American Medical Association,* 110 F. 2d 703, and where the indictment was made the subject of the identical descriptive adjectives as the Amended Complaint in the instant case, and the second question is answered by the reasonable conclusion that to maintain and preserve an existing criminal fact required criminal activity. This is no different than a criminal fact in gambling, prostitution or other criminal activity. It was extremely unfortunate that employees of the government allowed themselves to become involved through their superiors in this combination. But then again, it is impossible to maintain and preserve a criminal combination without some aid from those who are supposed to enforce the law. It would probably have been better judgment of the petitioners in the first instance to have named the government employees as mere conspirators instead of defendants. This is the first suit of its kind where the office of the Solicitor General and Attorney General have joined forces with a criminal combination in violation of the antitrust laws of Civil Rights Act. This juncture enables the American Medical Association to set up a fictitious defense as a law enforcement agency in validation of its criminal combination, and, therefore, "justify concerted criminal action to prevent the people from developing new methods of serving their needs." *American Medical Association* v. *United States,* 317 U.S. 519. Contrary to that decision this monopoly to enforce a law has a "license to commit crime."

The memorandum next states that:

> "The District Court, without considering the merits of the allegations regarding a conspiracy, found that the sponsors of Krebiozen had never made a bona fide attempt to have the drug licensed for interstate distribution under the provisions of the Federal Food,

> Drug, and Cosmetic Act and that it was this failure on the part of the sponsors to comply with the licensing procedure, rather than the alleged misconduct of respondents, which prevented and would continue to prevent the interstate distribution of Krebiozen."

This statement is totally inconsistent with the facts which are all around conceded by the respondents themselves, and the Court may only refer to pages 31-33 in the Petition for Certiorari: On three different occasions applications were made under section 355(a) and (b), Title 21, U.S.C., and all three were denied, not on the merits, but on the grounds that Krebiozen, because of its evident components, did not come within the provisions of the Federal Food, Drug, and Cosmetic Act, but instead, it came under the provisions of the Public Health Service Act, and that "Nothing is to be gained by considering the product as a new drug under the Food, Drug, and Cosmetic Act." It is the Solicitor General and the respondents who reject the scientific determinations of the Department of Health, Education and Welfare. Petitioners seek to enforce the determinations of this scientific expertise, not to challenge them. Coming, as it does, under the Public Health Service Act, Krebiozen when distributed interstate for "sale, barter or exchange" is subject to the penal provisions of section 262, Title 42, U.S.C. But absent the elements of "sale, barter or exchange" there is no restriction on interstate distribution for "use in scientific and experimental research." This has been the construction of this penal statute for half a century, 29 Opinion of Attorney General 340, and remains unquestioned to this day, nor has the Attorney General revised this Opinion. Moreover, he must give to this penal statute a strict construction. The District Court fully realized what relief the petitioners sought when it said that:

> "The prayer for relief seeks an order enjoining the defendants 'from impeding, hindering, or impairing the free *uncommercial* flow of Krebiozen interstate . . . to the physicians of the plaintiffs . . . for the purpose of continuing experimentation on the plaintiffs by their doctors'."

This brings up a question of construction of a law of the United States where the petitioners could be sustained on one construction and defeated on the point by an opposite construction, and therefore it is jurisdictional. *Bell* v. *Hood*, 327 U.S. 678; *The Fair* v. *Kohler Die and Specialty Company*, 228 U.S. 22. However, sustaining the petitioners would not be sufficient if the conspiracy is left unjoined. The conclusive proof of this can be inferred from the fact that for thirteen years prior to any challenge to interstate distribution of Krebiozen for "use in scientific and experimental research" the conspiracy existed. A construction of section 355(i), Title 21, U.S.C. is also involved. This new amendment, effective in June 1963, relates only to drugs covered by the sub-sections foregoing sub-section (i) to "enable him (the Secretary) to evaluate the safety and effectiveness of such drug *in the event of the filing of an application pursuant to* sub-section (b)." Section 355(i)(3), Title 21, U.S.C. Since the scientific expertise of the Department of Health, Education, and Welfare has determined that, where Krebiozen is concerned, there can be no valid effective application pursuant to section 355(b), Title 21, U.S.C., the amendment to sub-section (i) can have no application, and any regulations promulgated by the Secretary extended beyond the express words of the statute would not be regulation but legislation, and unconstitutional. This question like the question before it is jurisdictional as petitioners could be sustained by one construction and defeated on the point by an opposite

construction. That these two questions are jurisdictional was admitted by the Court of Appeals in *Rutherford et al.* v. *American Medical Association,* 379 F. 2d 641, 644 as follows:

> "The first four questions asked are jurisdictional in nature and involve the construction of various federal statutes considered here in, *inter alia,* the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, the Sherman Antitrust Act, and the Federal Civil Rights Act. The fifth and sixth questions concern a determination of whether the American Medical Association and the American Cancer Society are subject to the restrictions and prohibitions contained in the fourteenth Amendment and the Civil Rights Act.
>
> " . . . In view of our disposition of this appeal, plaintiffs are left with the right to seek review thereof by petition to the Supreme Court for a Writ of Certiorari."

This Memorandum correctly recognizes that the Petitioners allege that the "Respondents combined and conspired to discredit the medical efficacy of the alleged anticancer drug, Krebiozen, and to impede the interstate distribution of that drug to those who wished access to it."

However, it then, in error of fact, misstates that "Petitioners alleged that the American Cancer Society (allegedly a part owner of the anticancer drug, 5-FU) secured a monopoly in the distribution of anticancer drugs and that the impediment to the interstate distribution deprived petitioners of their civil rights." This is "confusion worse-compounded," perhaps resulting from lack of sufficient acquaintance with the pleadings.

What the Petitioners allege is not that the Petitioners were deprived of their civil rights because of any monopoly of the American Cancer Society in the distribution of

anticancer drugs. The Petitioners would have supposed that it is common knowledge that the American Cancer Society has no charter authority to distribute any drugs and, of course, the Petitioners could hardly have alleged that it has any monopoly in such distribution.

What the Petitioners do allege, as they have striven in every way to communicate in their pleadings, is that it is the American Medical Association which has a monopoly, not in the distribution of anticancer drugs, but in the "trade of medicine". *American Medical Association v. United States,* 130 F. 2d 233, affirmed 317 U.S. 519. If there is any question in the mind of the Solicitor General as to whether such a monopoly does in fact exist *he need only refer to the indictment which he himself filed in that case.* (Record of that case, Vol. 1, pp. 7-20).

The writ of certiorari should be granted, the judgment of the United States Court of Appeals vacated, and the cause remanded to the District Court for a hearing on the facts alleged in the complaint, or in the alternative, the writ of certiorari should be granted and the case heard on the merits by this Court.

Respectfully submitted,

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